US009220544B2

(12) **United States Patent**
Matityahu et al.

(10) **Patent No.: US 9,220,544 B2**
(45) **Date of Patent: Dec. 29, 2015**

(54) **IMPLANTABLE DEVICE WITH LOCKING ADJUSTMENT MECHANISM AND METHOD FOR USING SAME**

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(72) Inventors: **Amir M. Matityahu**, Los Altos, CA (US); **Benjamin Clawson**, Santa Cruz, CA (US); **Alan Grantz**, Aptos, CA (US)

(73) Assignee: **Epix Orthopaedics, Inc.**, Los Altos, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/716,079**

(22) Filed: **Dec. 14, 2012**

(65) **Prior Publication Data**

US 2014/0012259 A1 Jan. 9, 2014

Related U.S. Application Data

(60) Provisional application No. 61/576,280, filed on Dec. 15, 2011.

(51) **Int. Cl.**
A61B 17/72 (2006.01)
A61B 17/74 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/7241*** (2013.01); ***A61B 17/744*** (2013.01); ***A61B 17/748*** (2013.01)

(58) **Field of Classification Search**
CPC ... A61B 17/724; A61B 17/748; A61B 17/744
USPC 606/62–68
See application file for complete search history.

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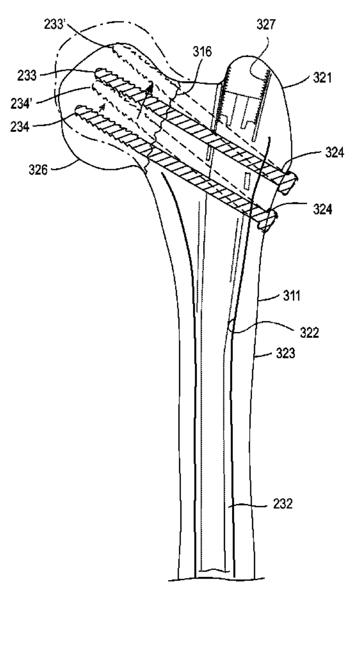
Primary Examiner — Pedro Philogene
Assistant Examiner — David Comstock
(74) *Attorney, Agent, or Firm* — Intellectual Innovations Legal Advisors

(57) **ABSTRACT**

An intramedullary rod for use in a mammalian body comprising an elongate nail having a stem and a head and a threaded element carried by the head and accessible at the proximal end for rotation relative to the head. A locking mechanism coupled to the threaded element and configured to preclude rotation of the threaded element relative to the head when the locking mechanism is in a first position and permit rotation of the threaded element relative to the head when the locking mechanism is in a second position.

24 Claims, 37 Drawing Sheets



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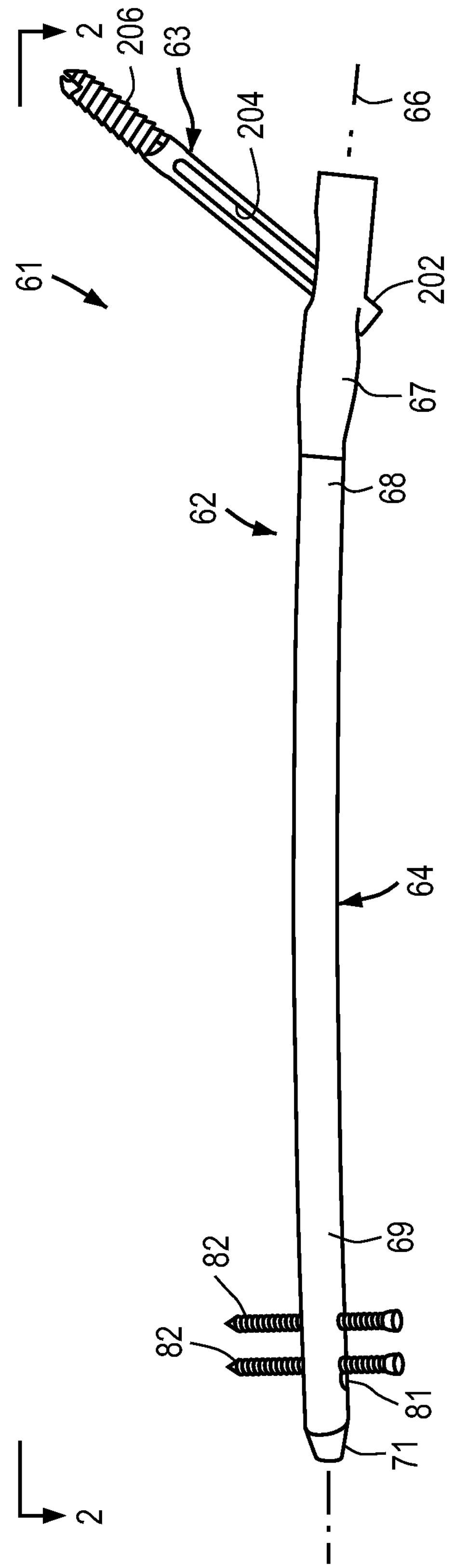
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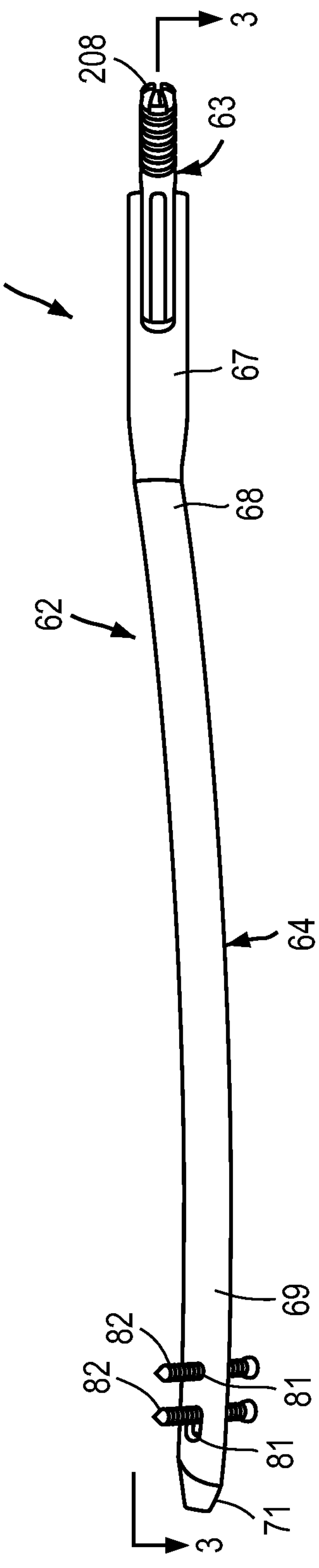
FIG.1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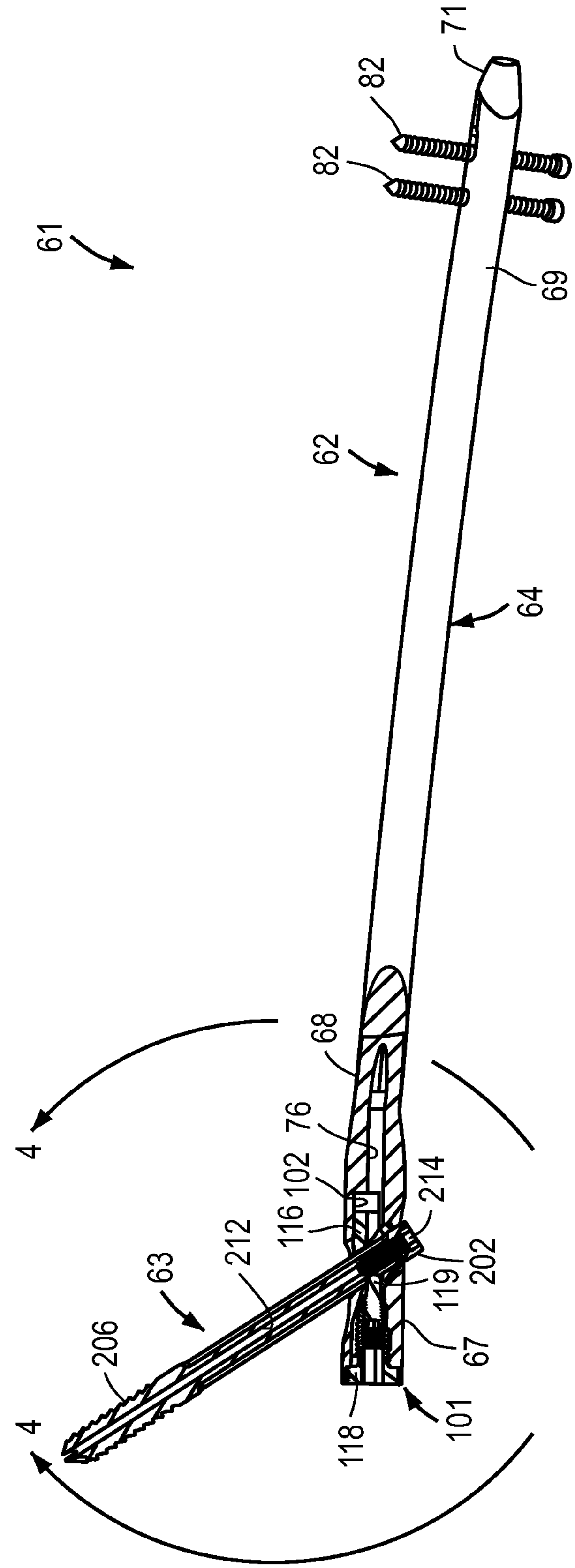

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FIG.3

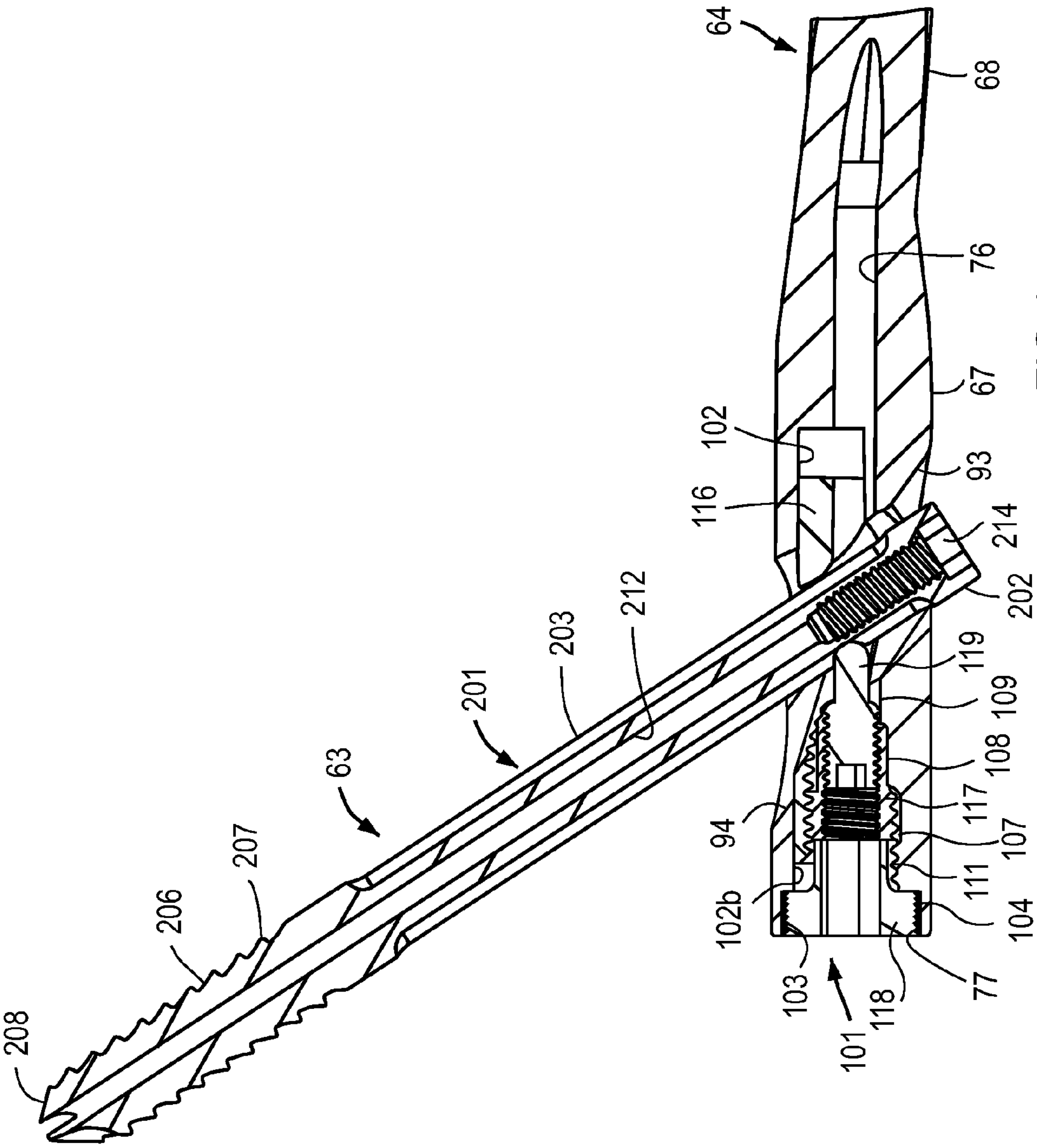
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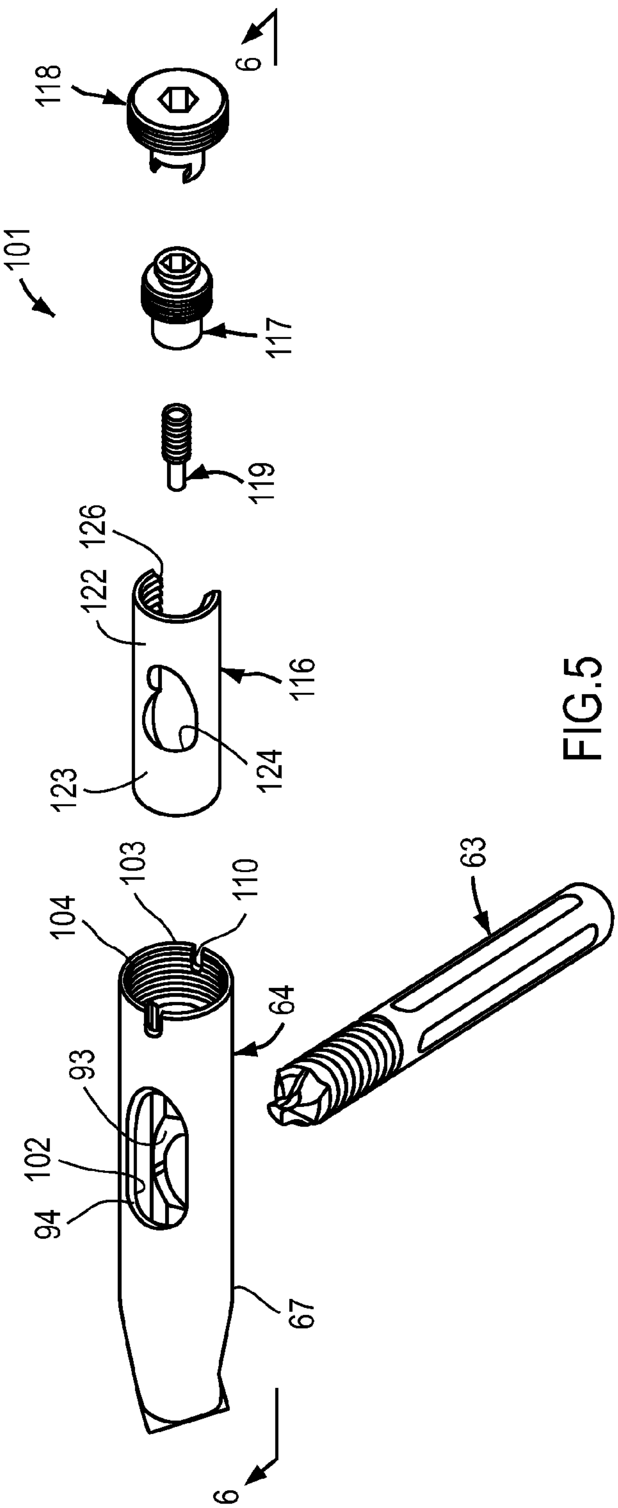
FIG.4



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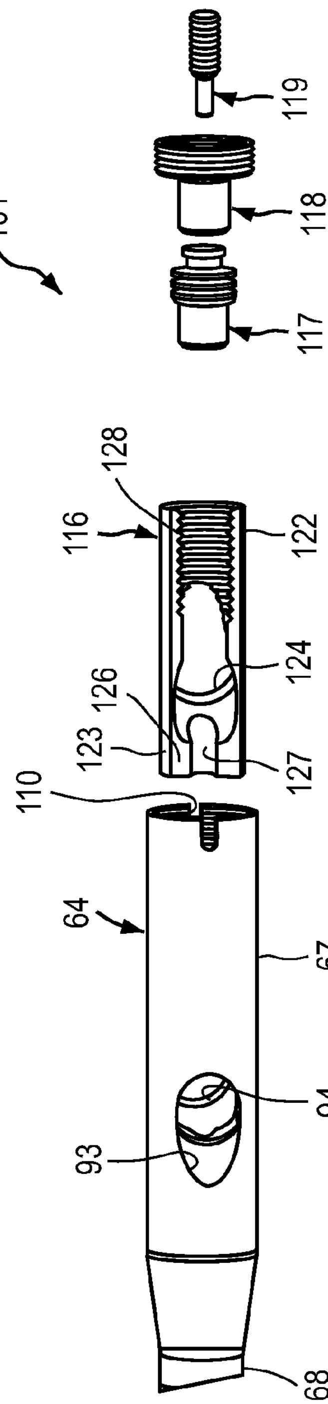

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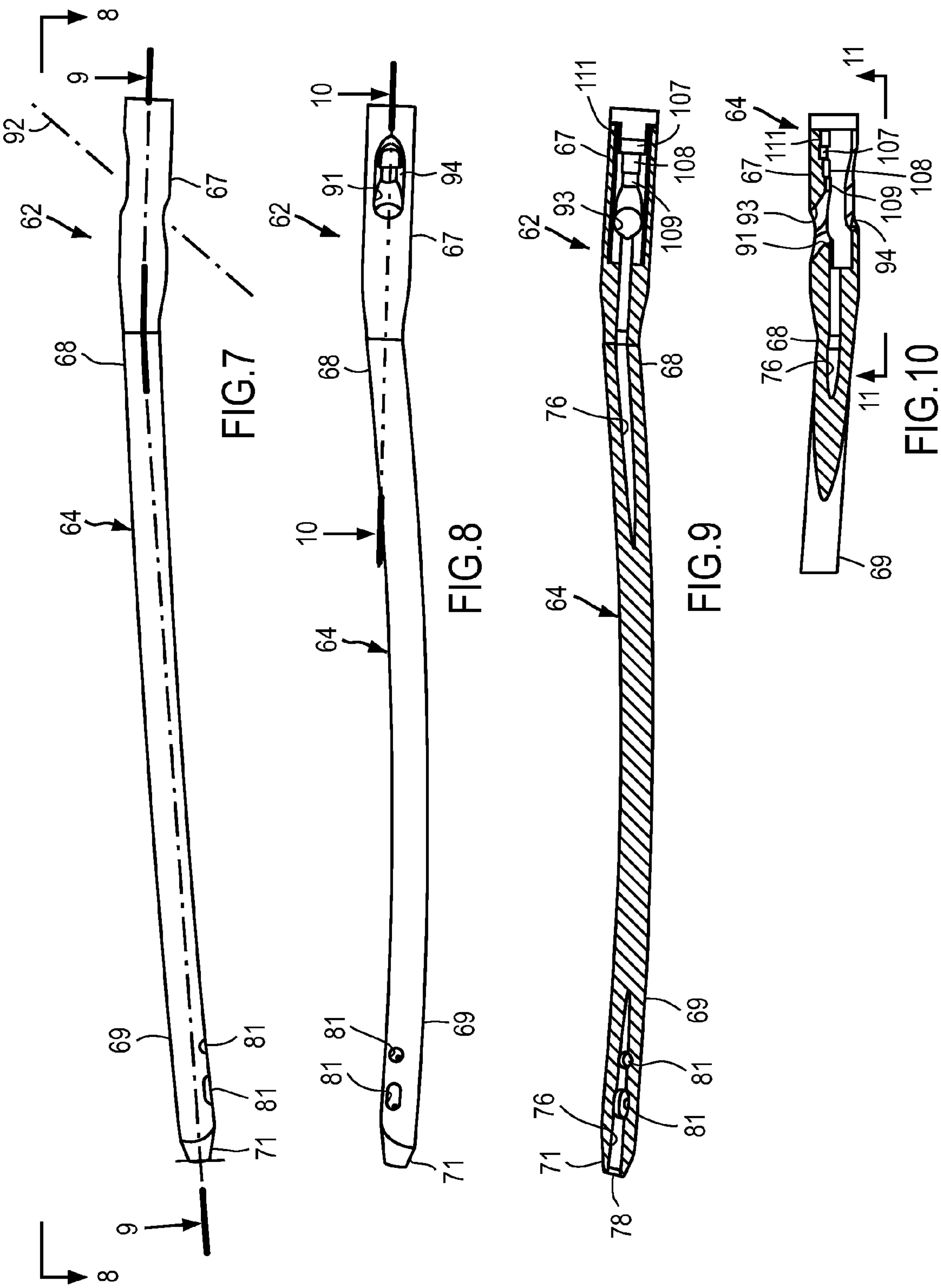

FIG.7

FIG.8

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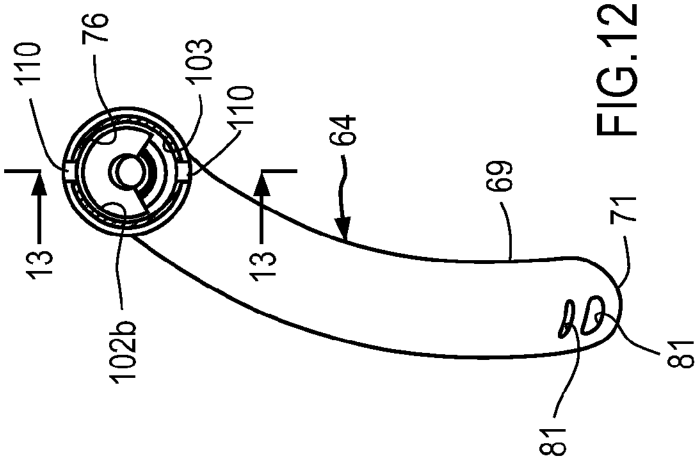

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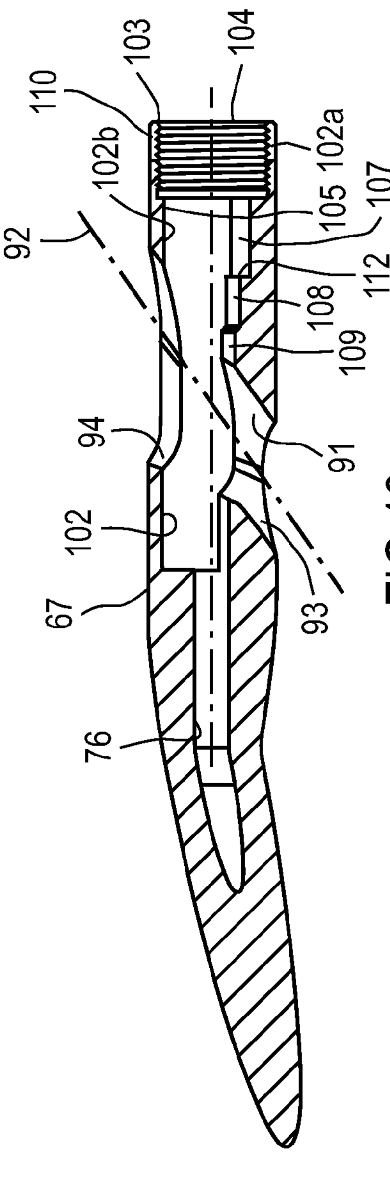

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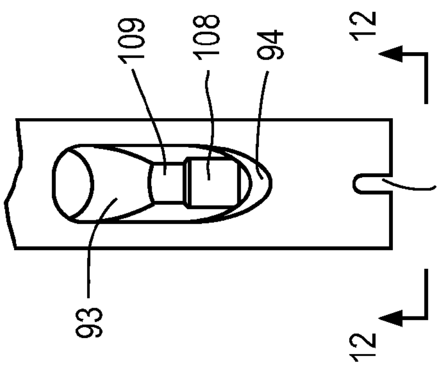

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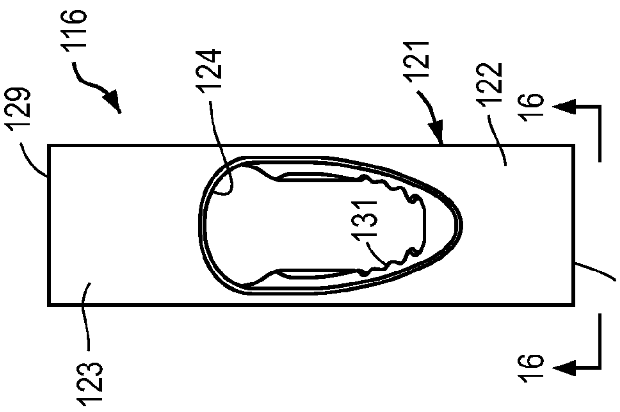

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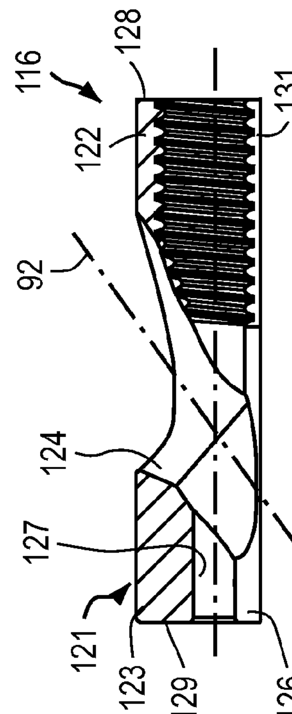

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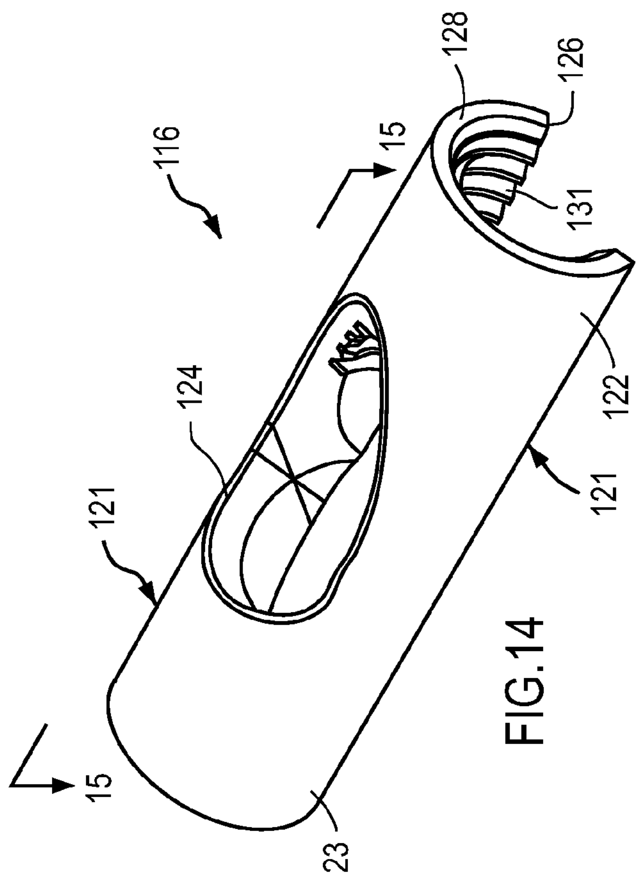

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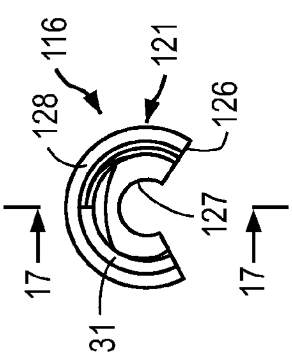

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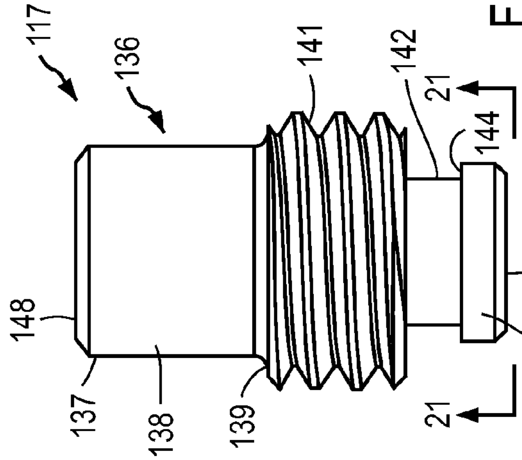

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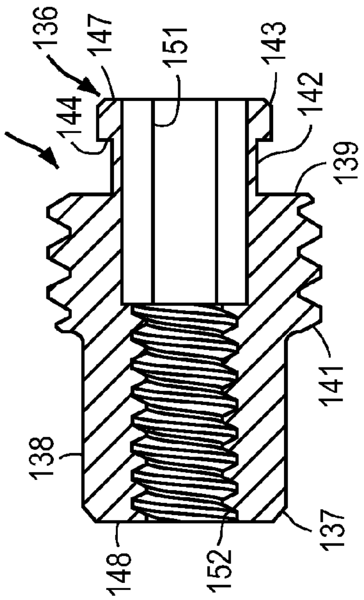

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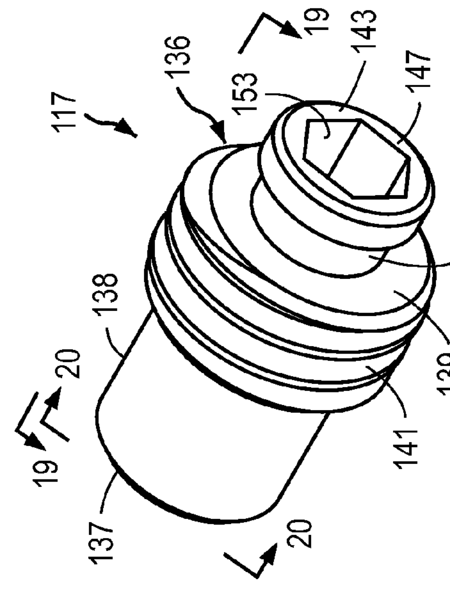

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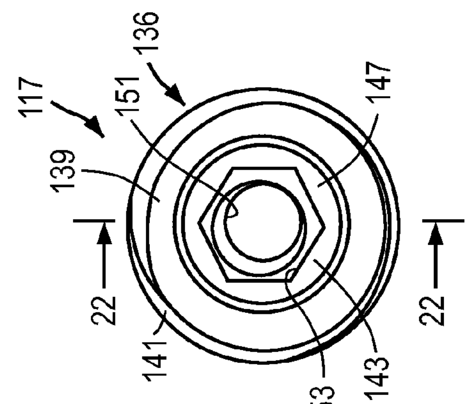

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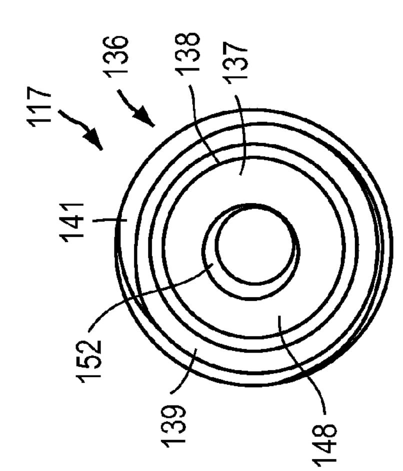

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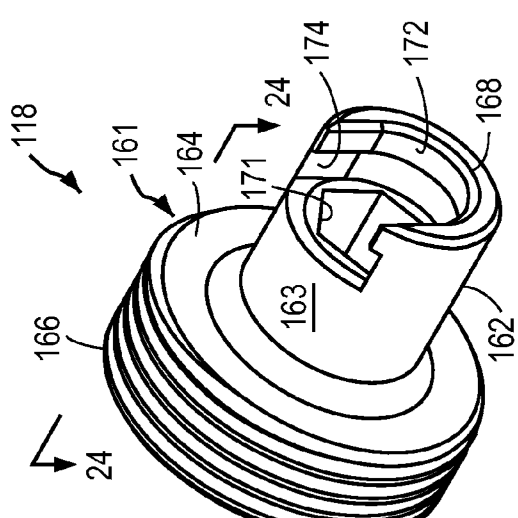

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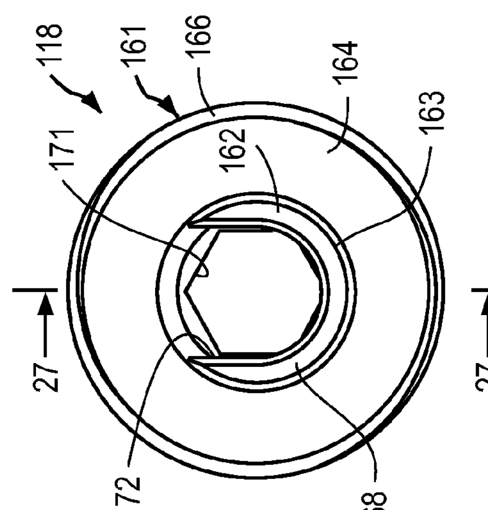

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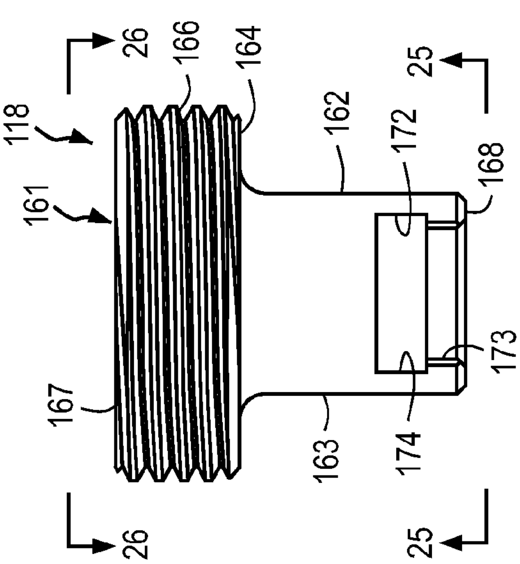

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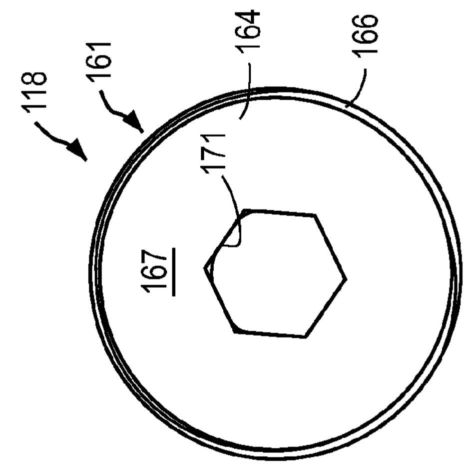

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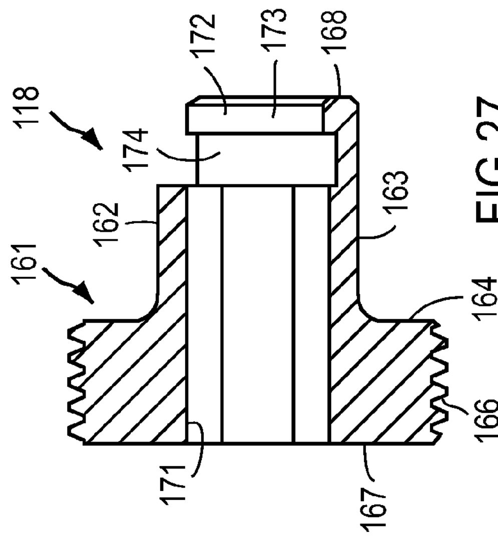

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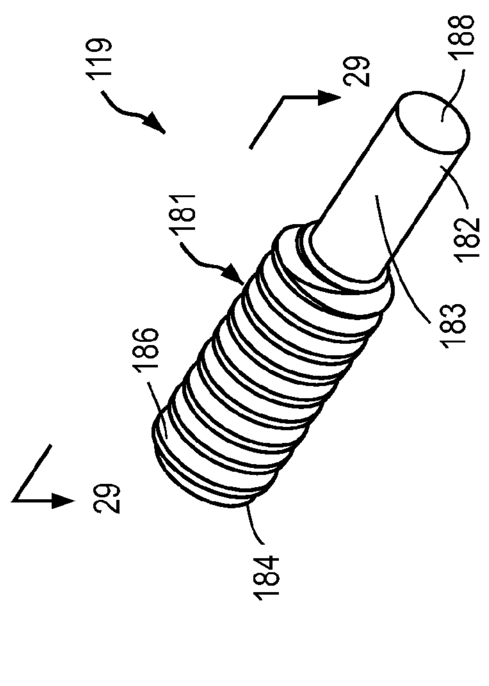

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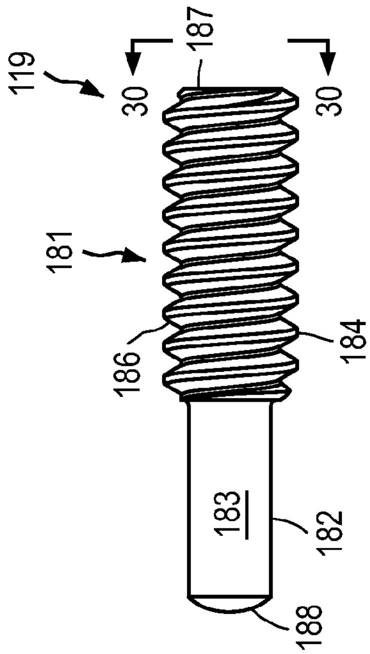

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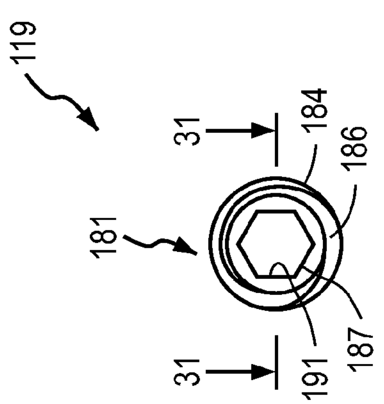

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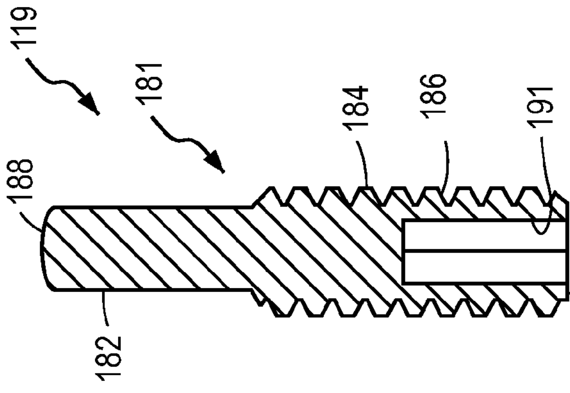

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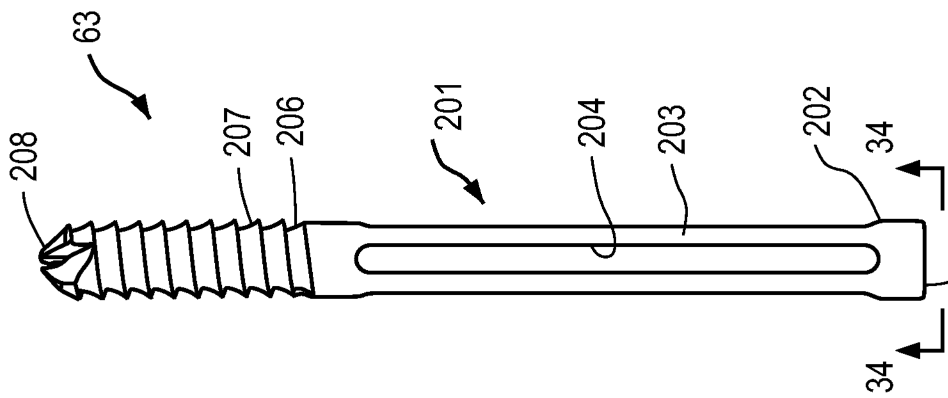

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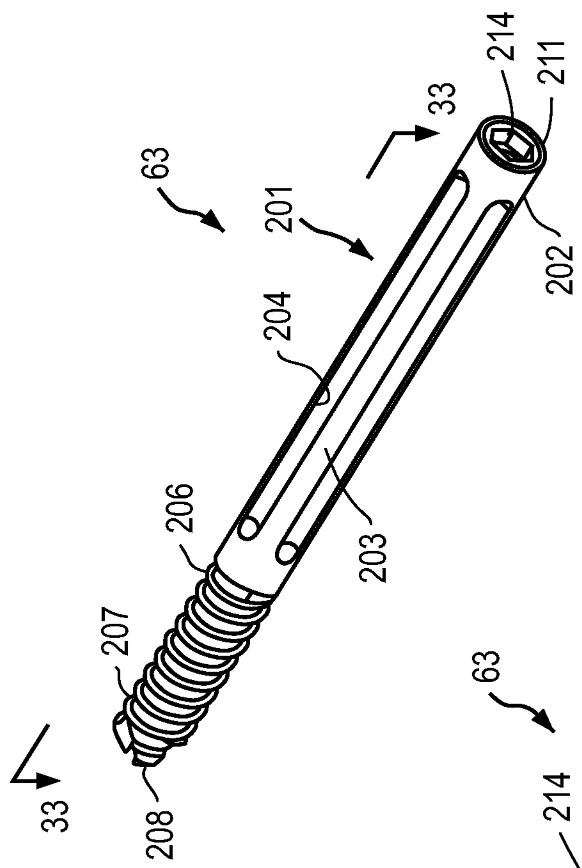

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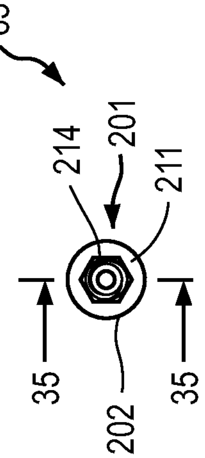

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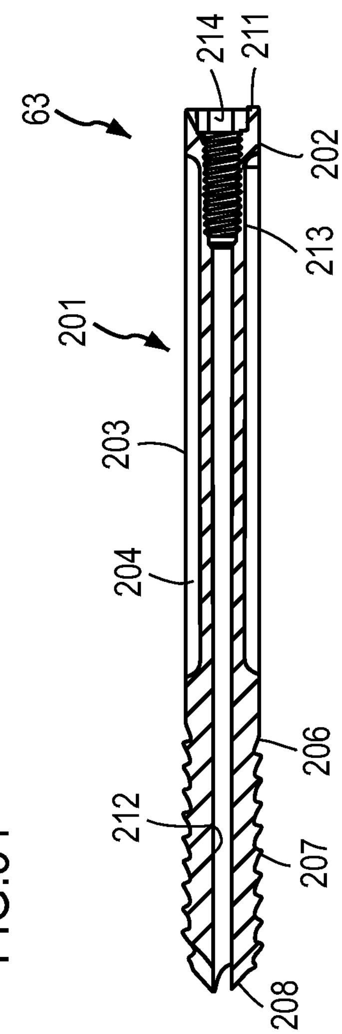

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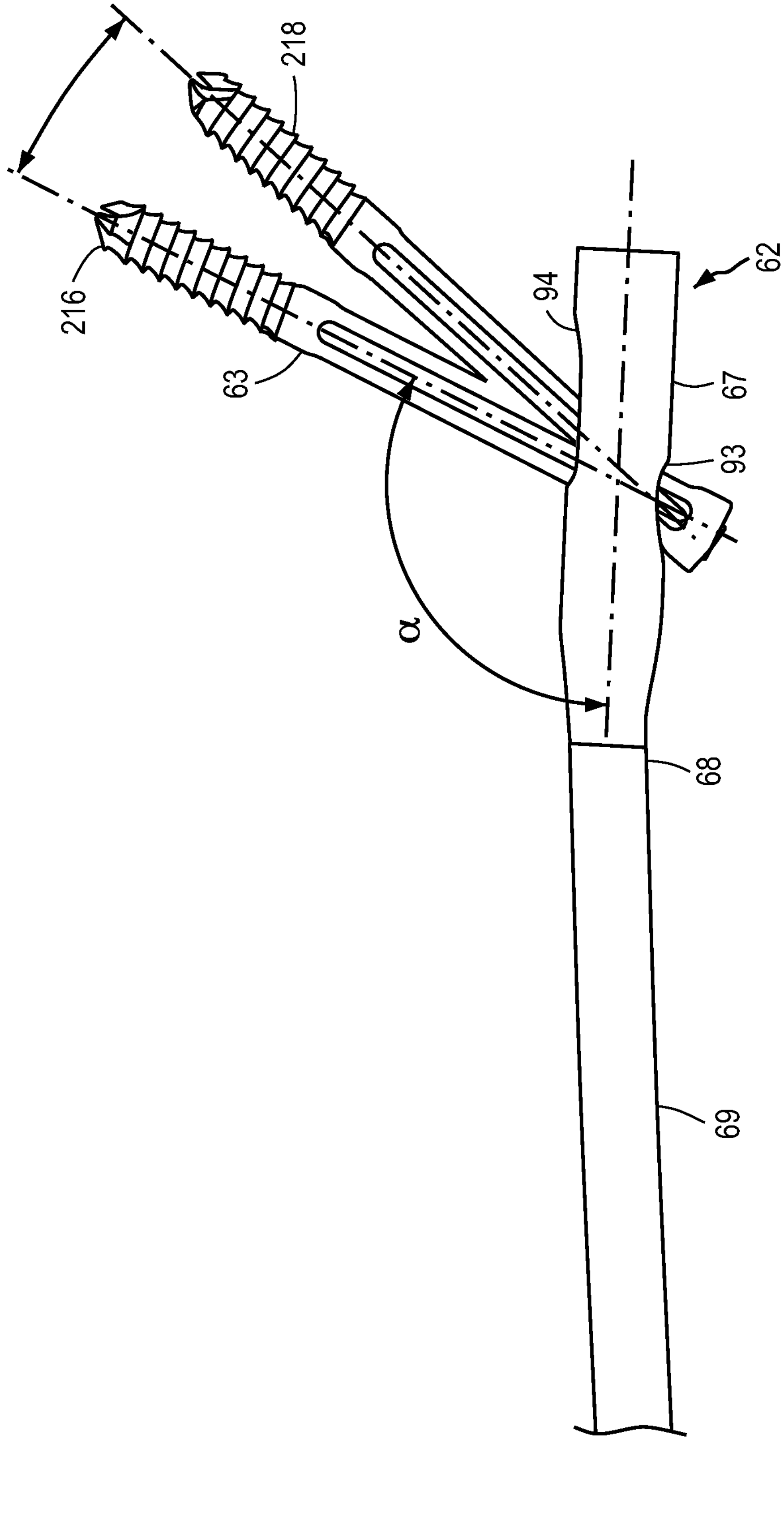

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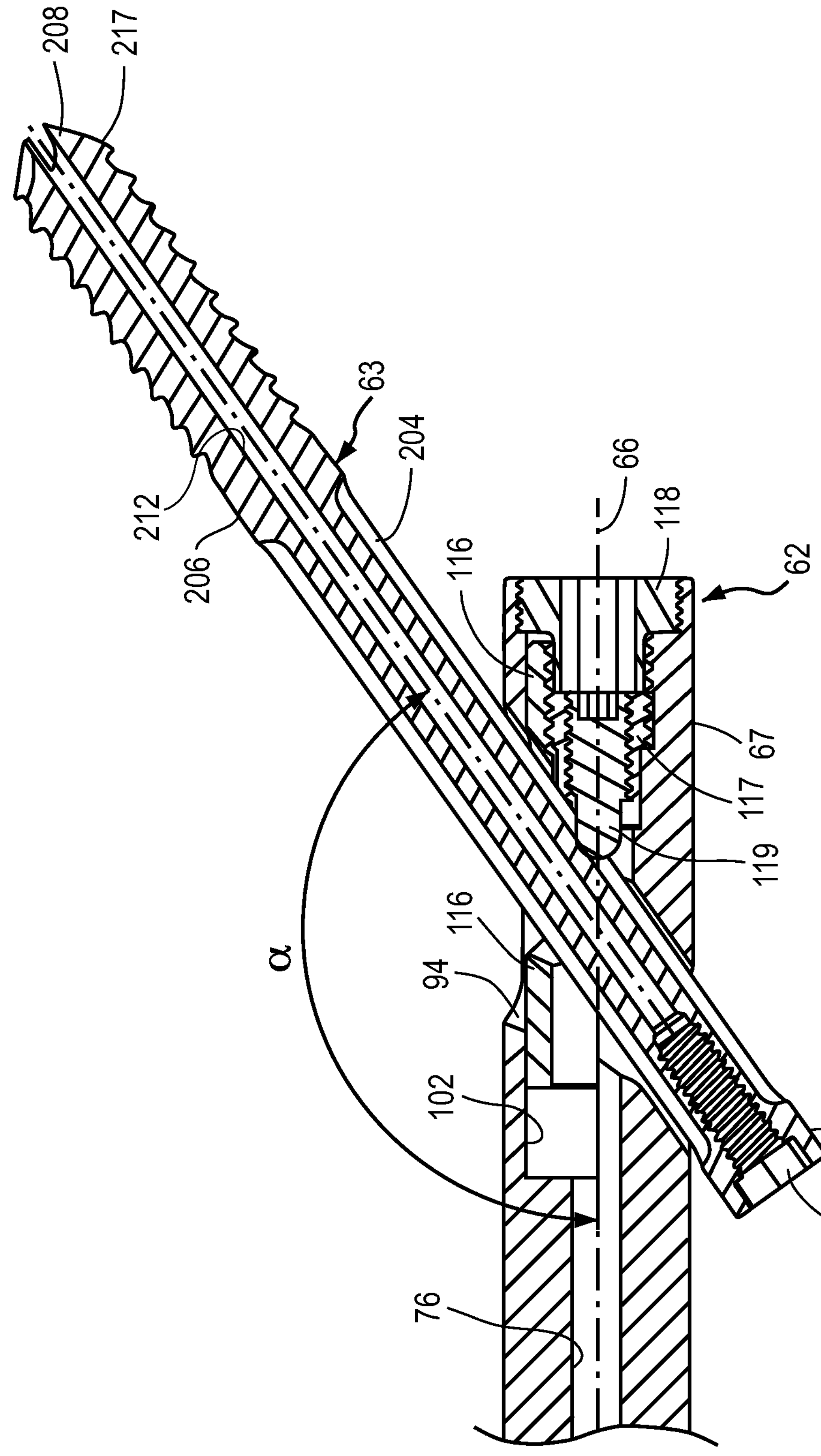
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FIG.37

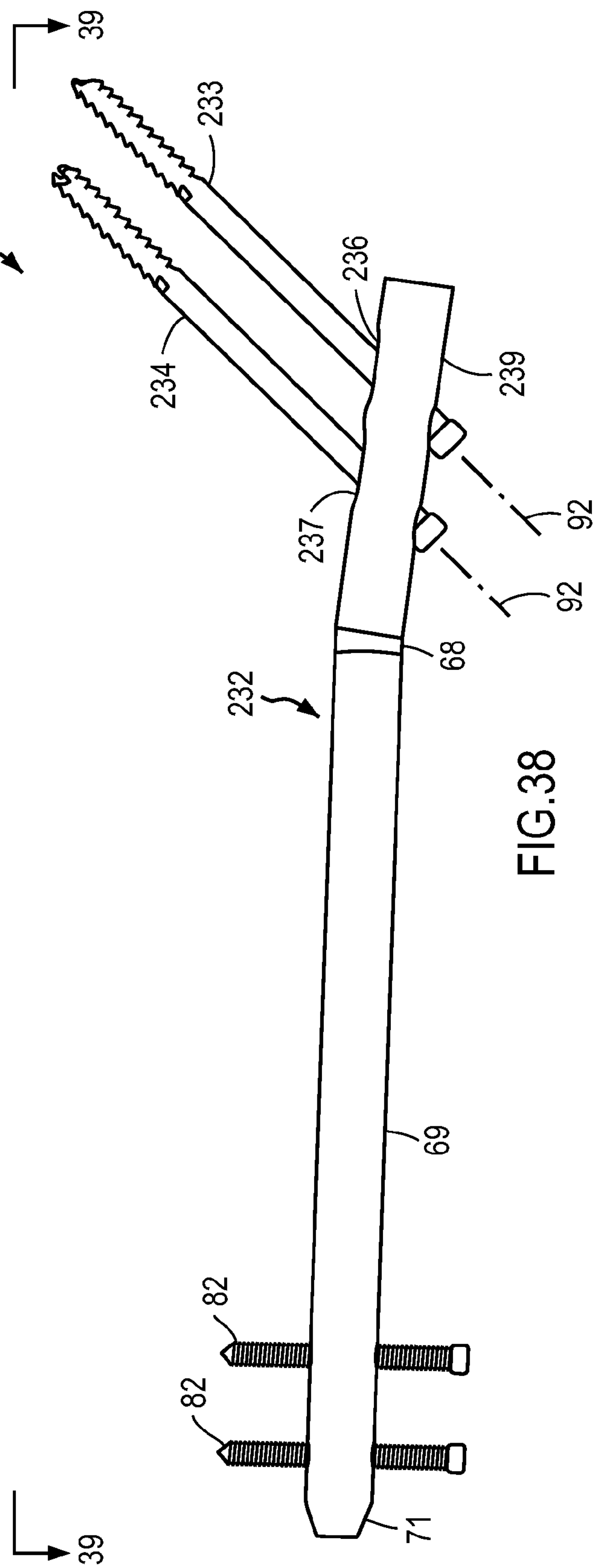
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FIG.38

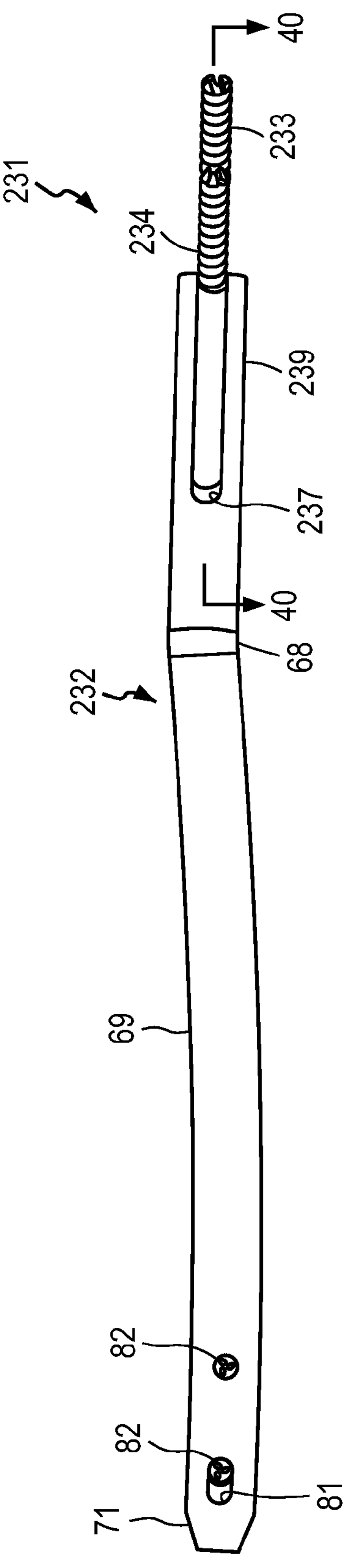
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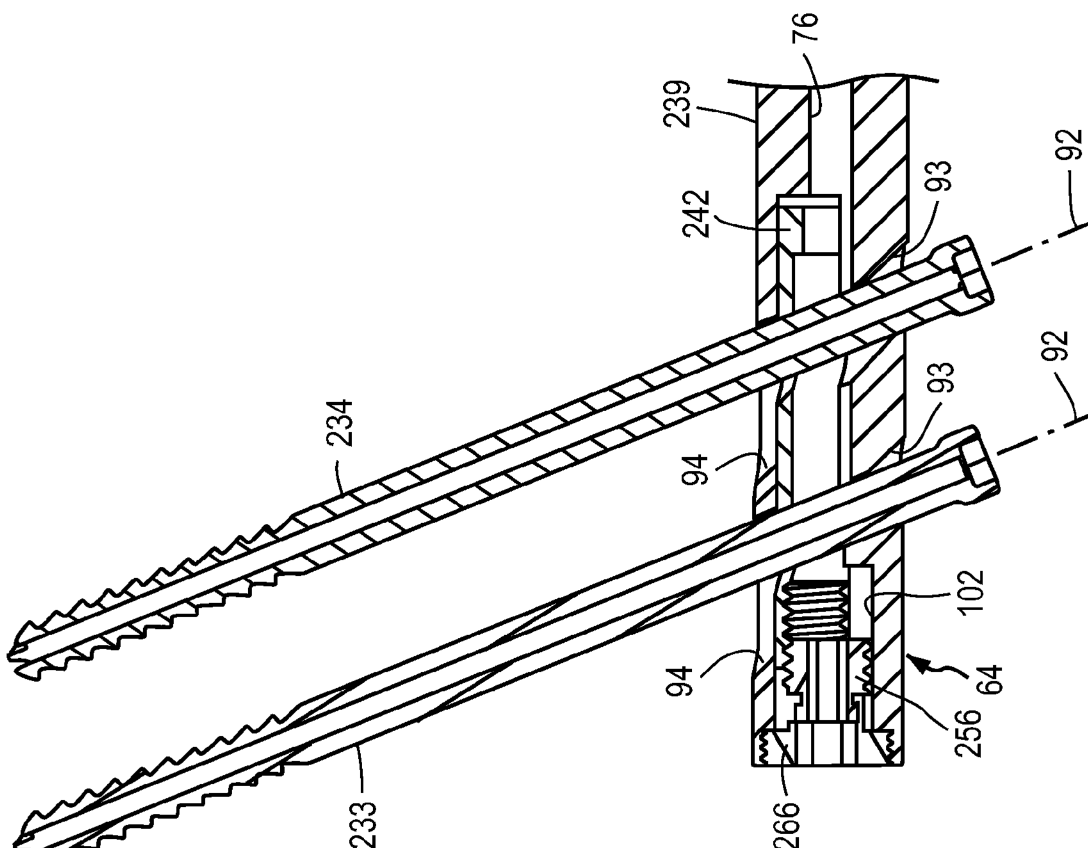
FIG.39



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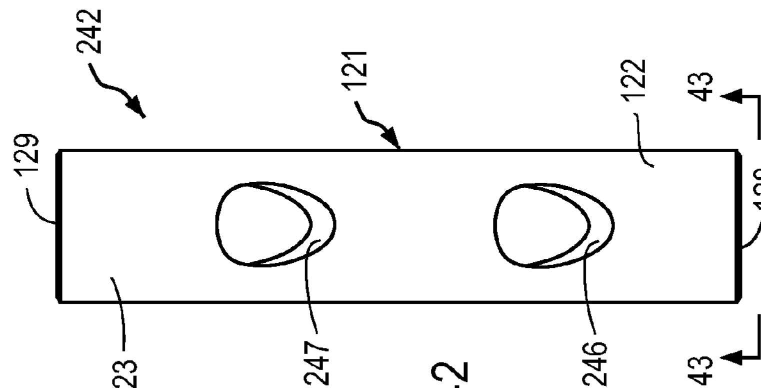

FIG.42

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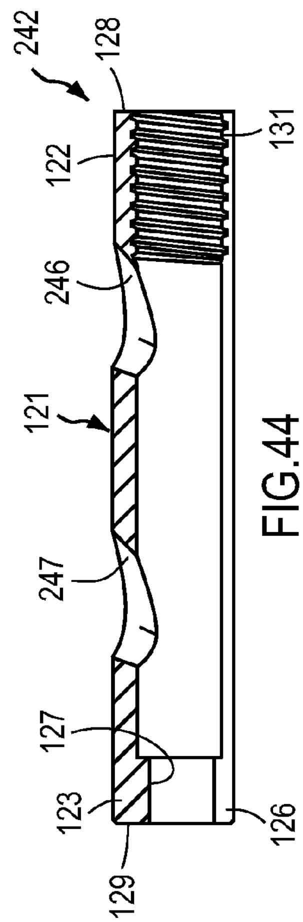

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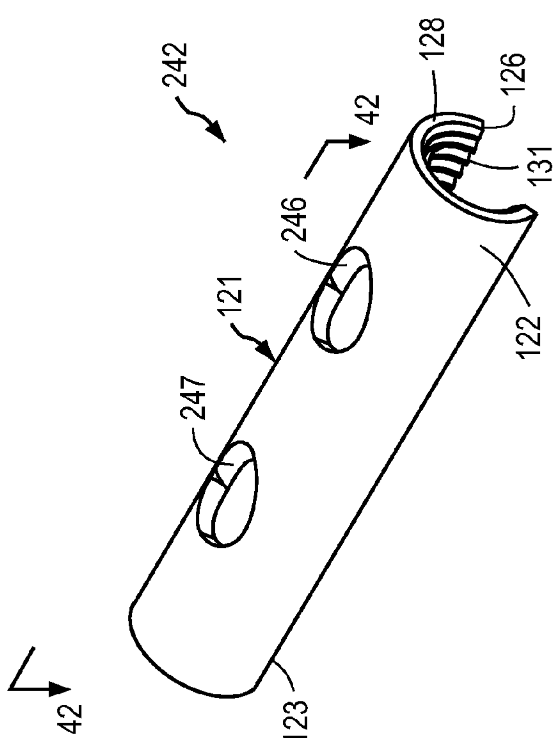

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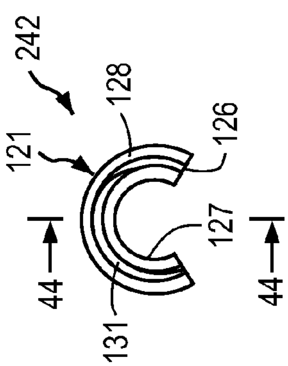

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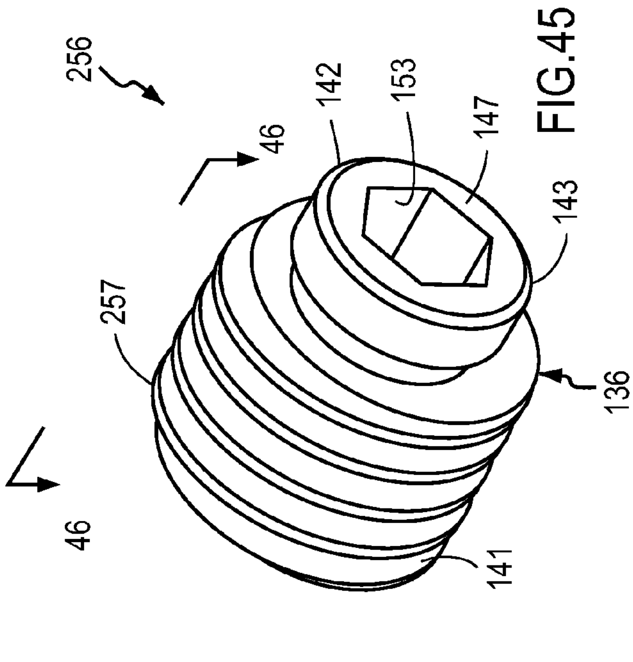

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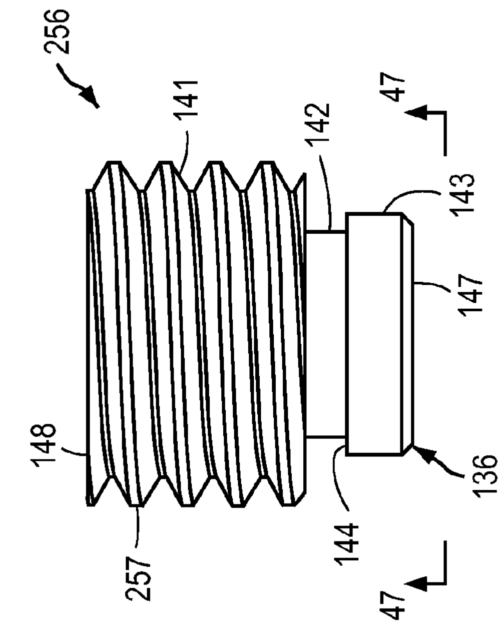

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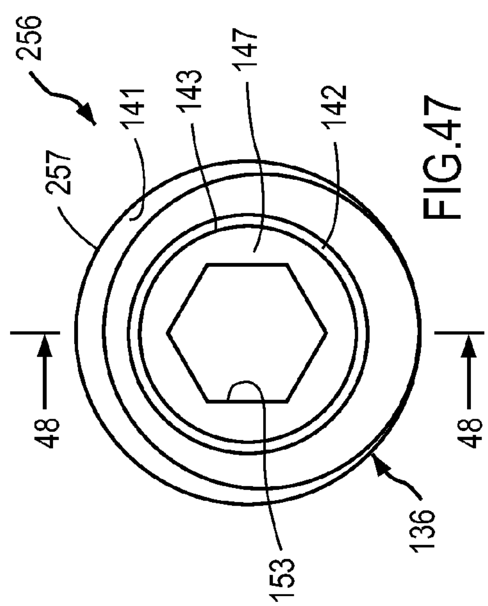

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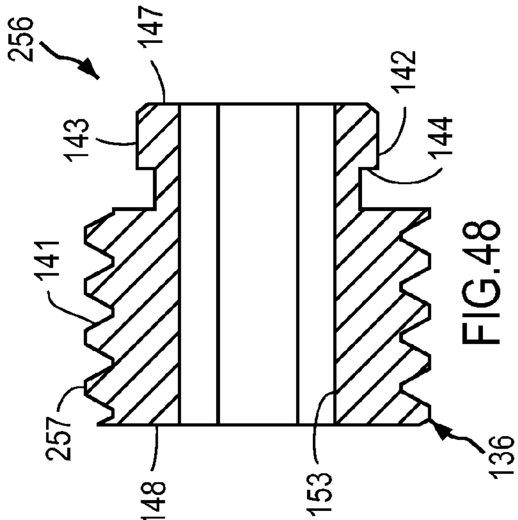

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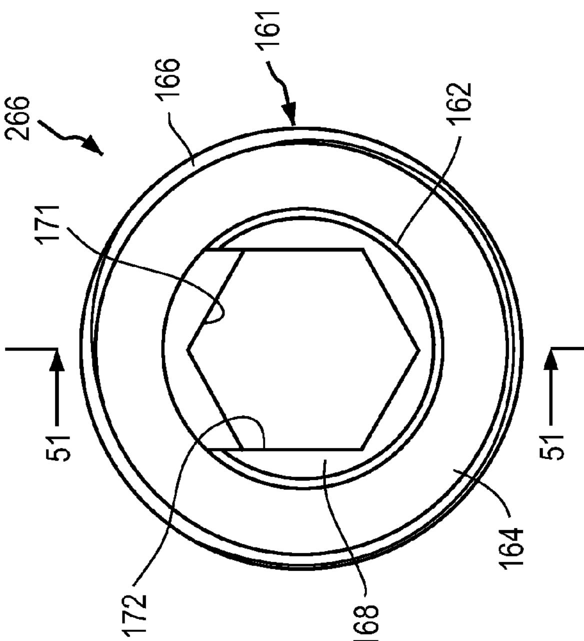

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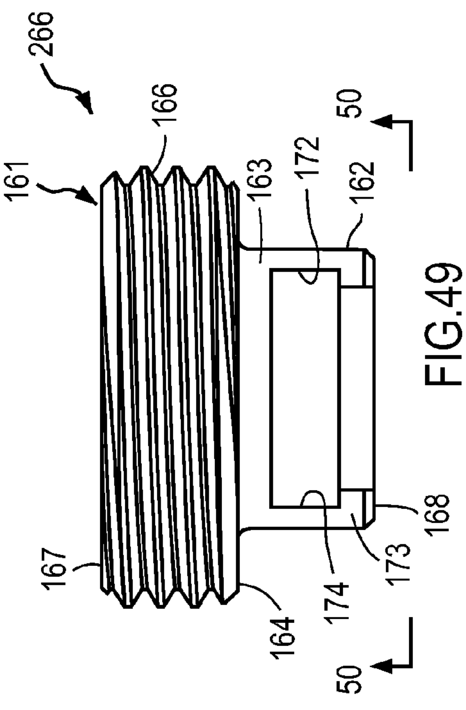

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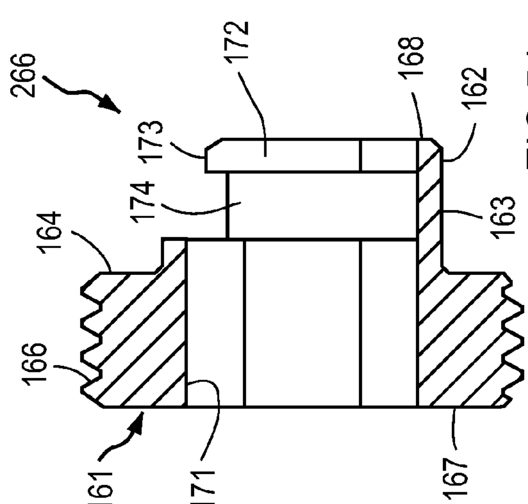
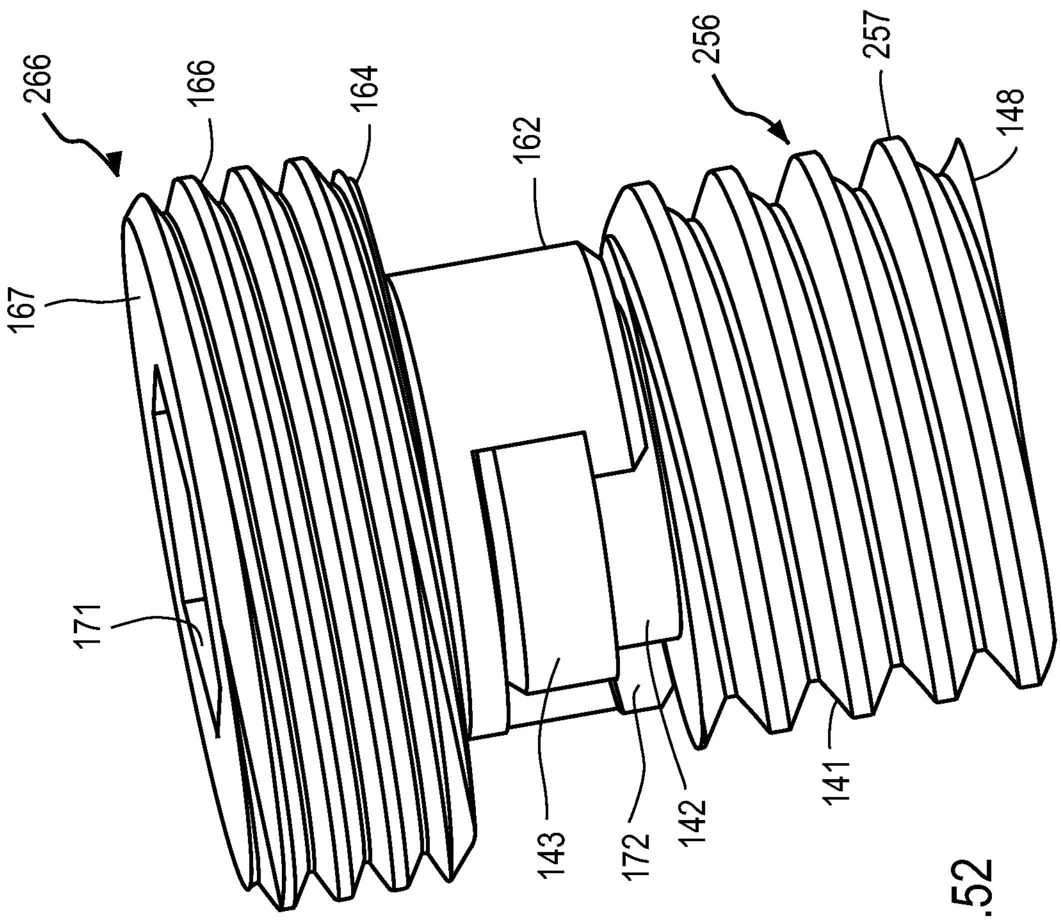


FIG.51



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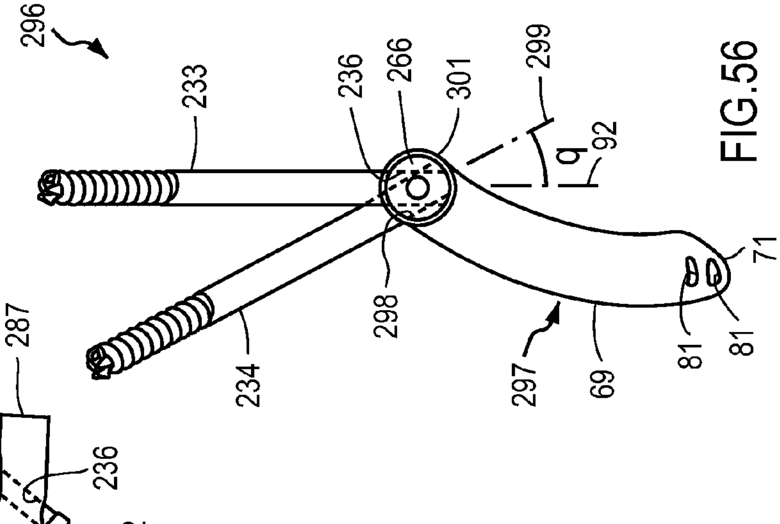
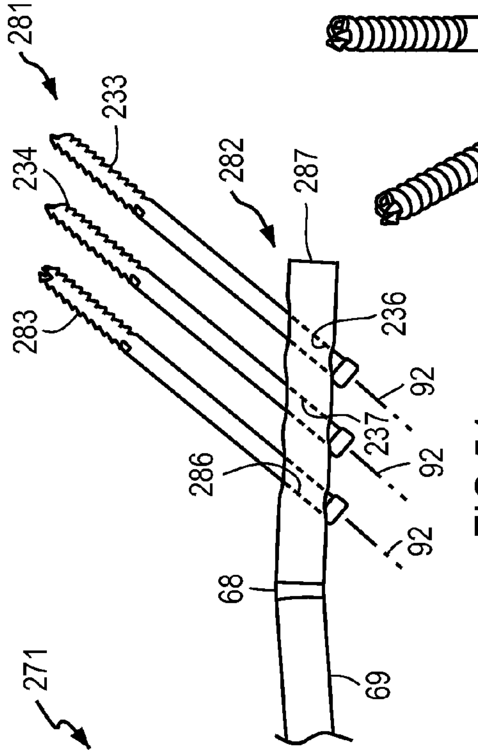


FIG.56



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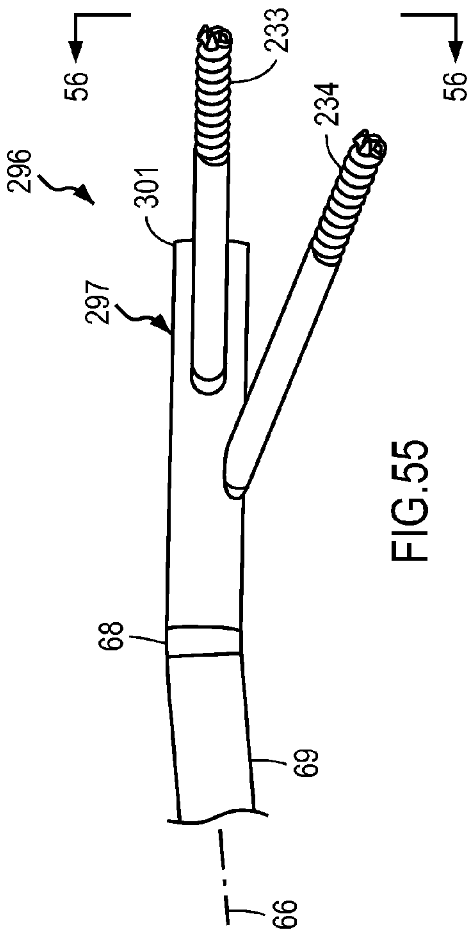
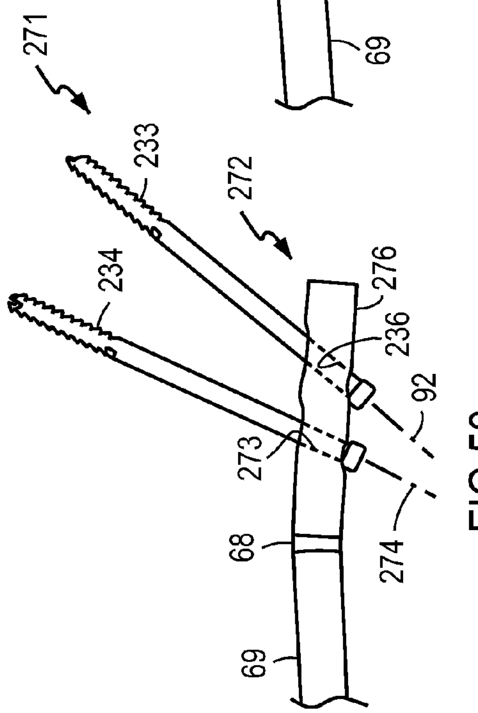


FIG.55



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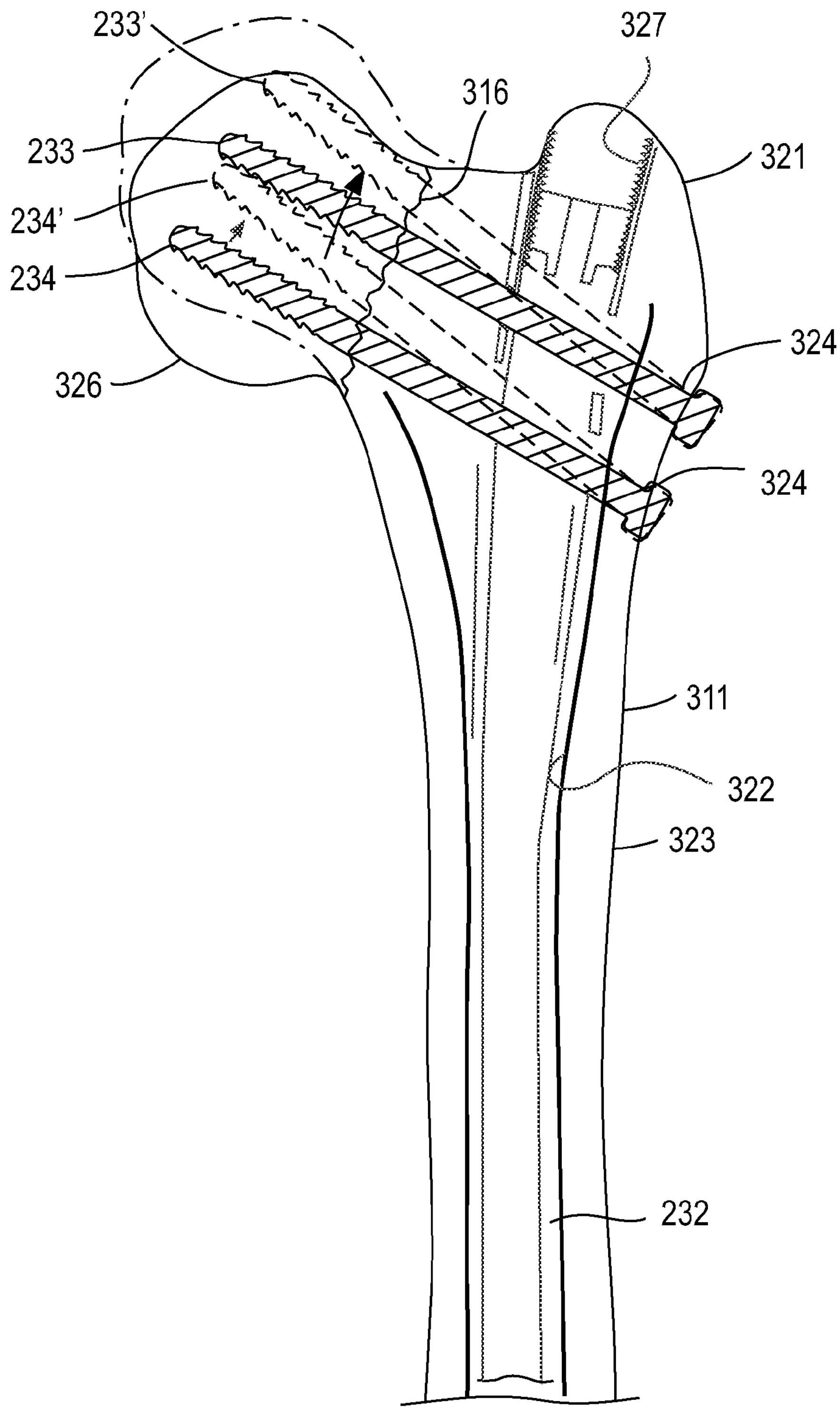

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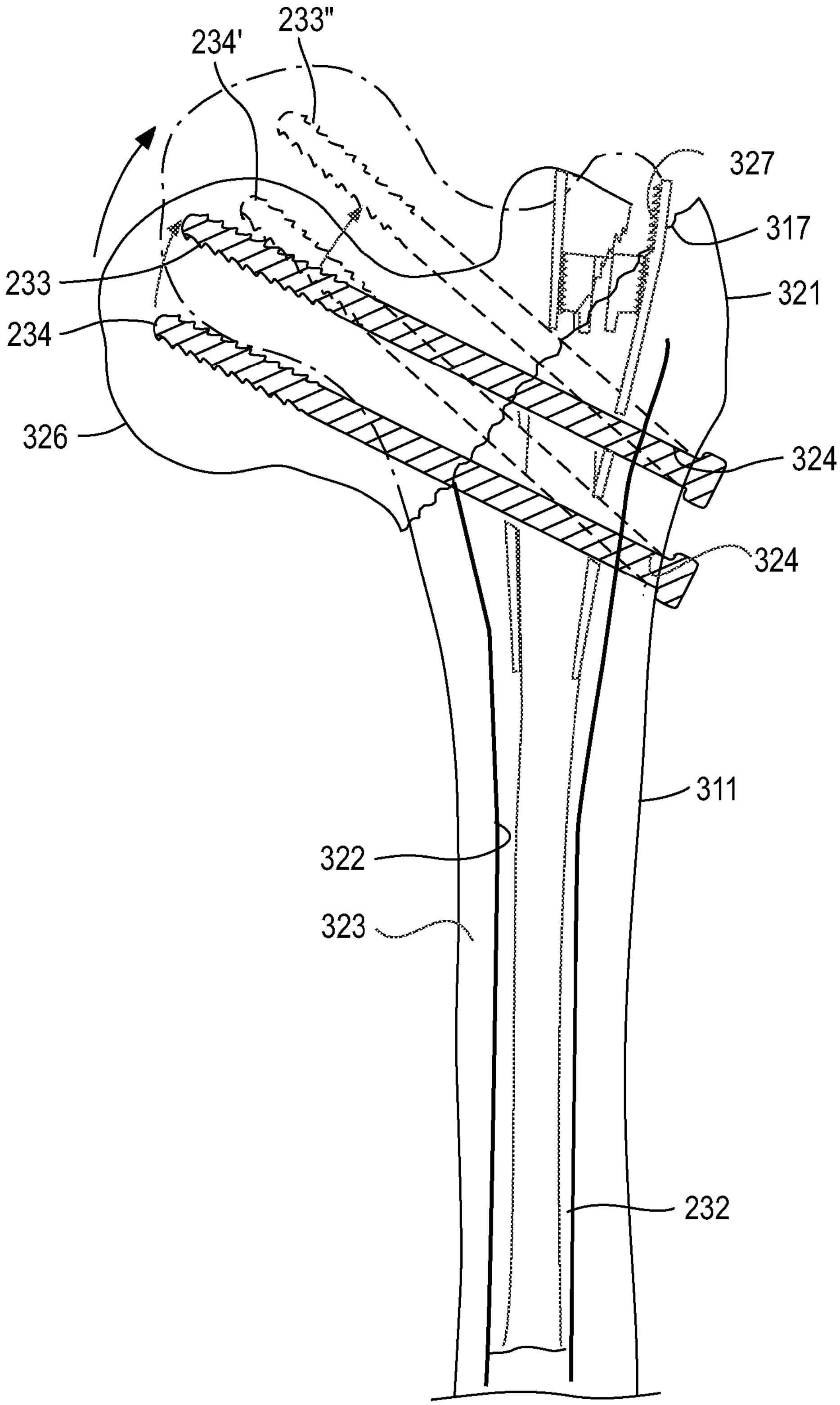

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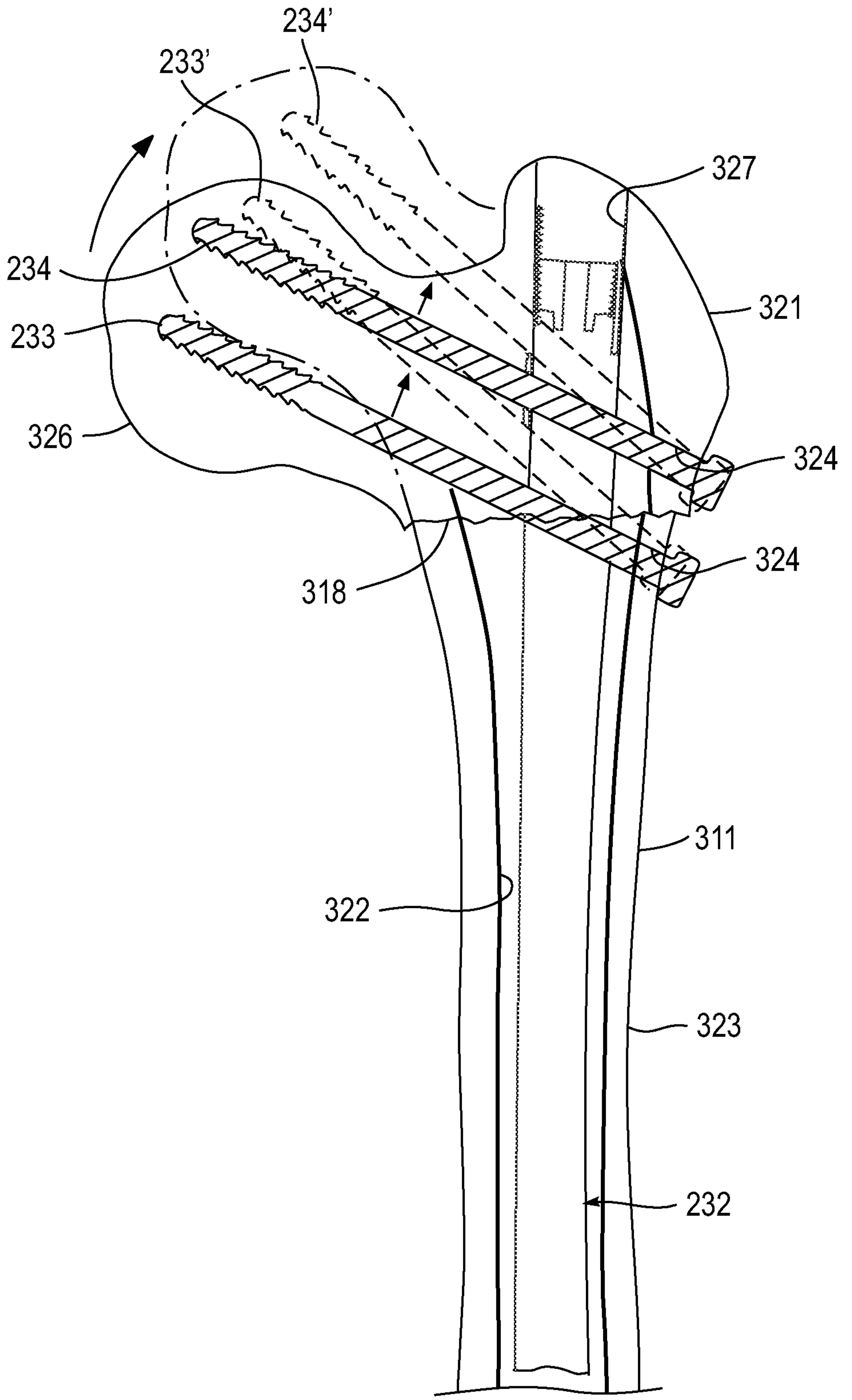

FIG. 59

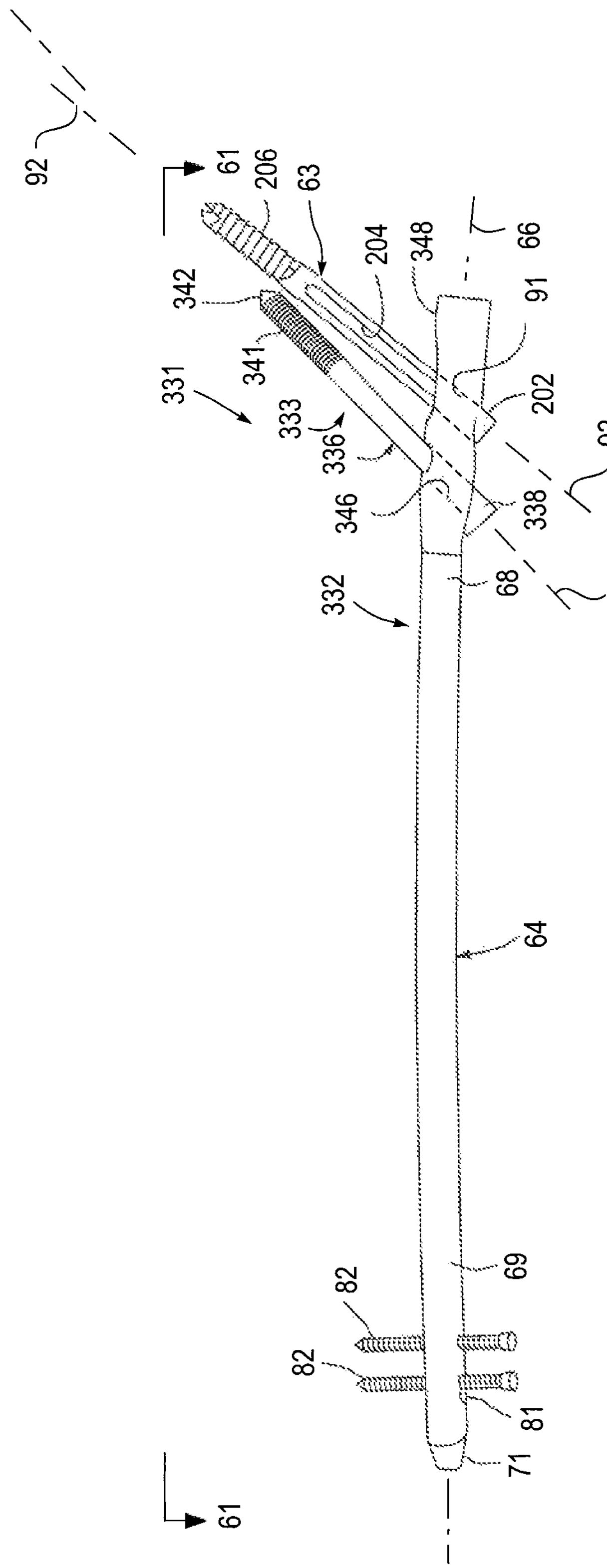
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FIG. 60

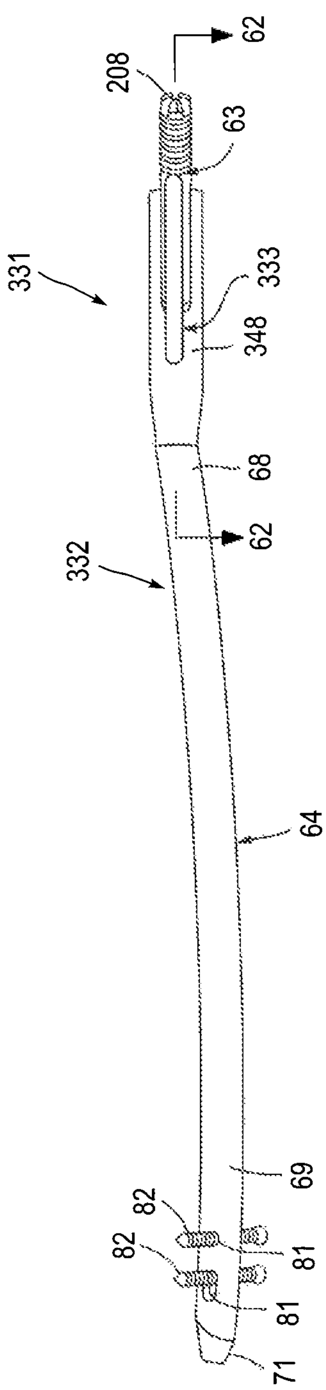
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FIG. 61

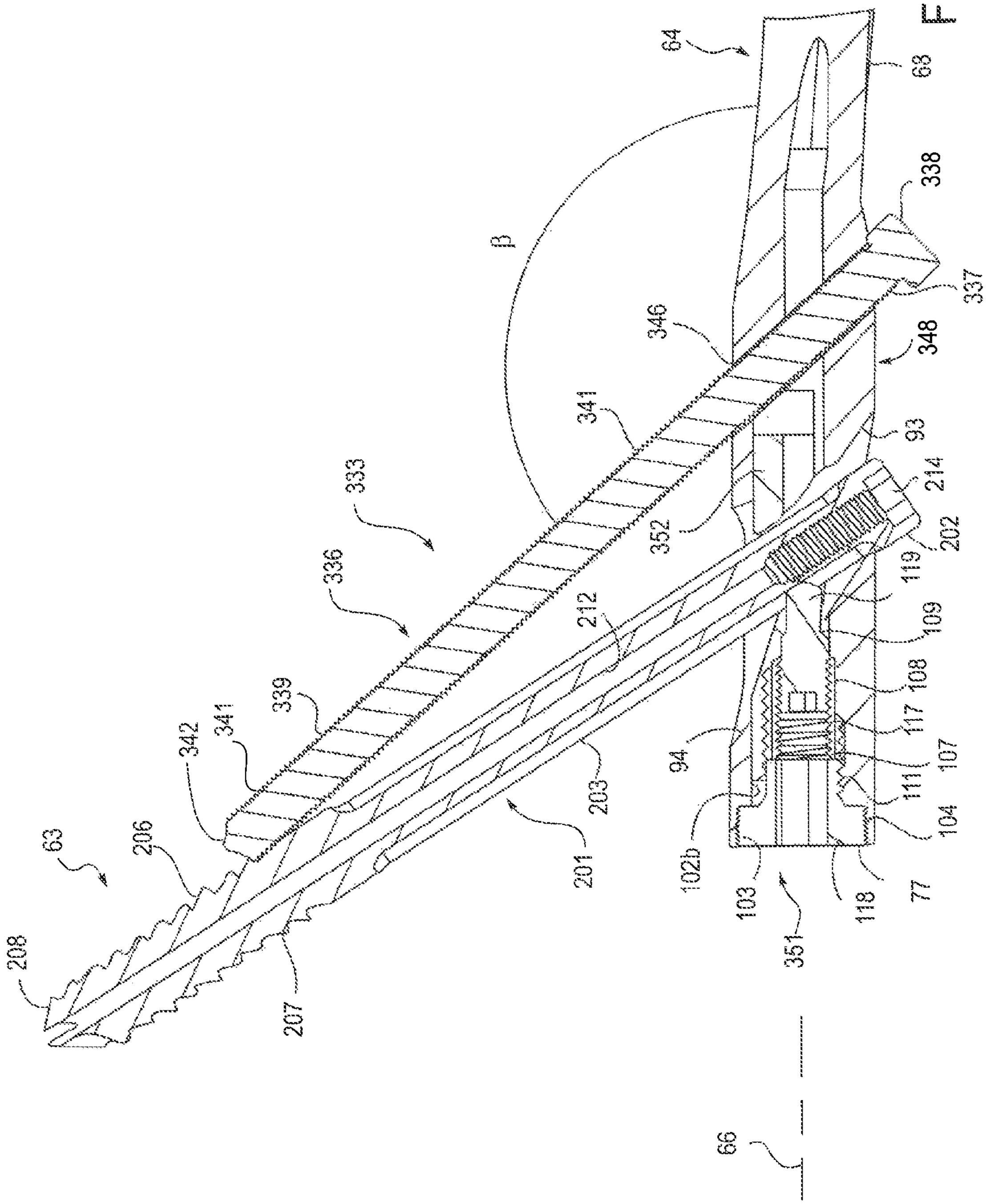
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FIG. 62

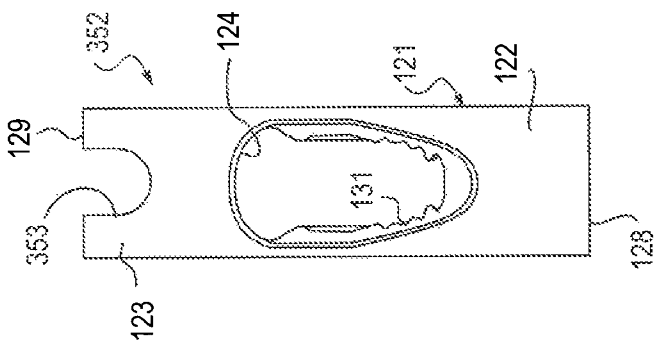
352
124
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FIG. 64

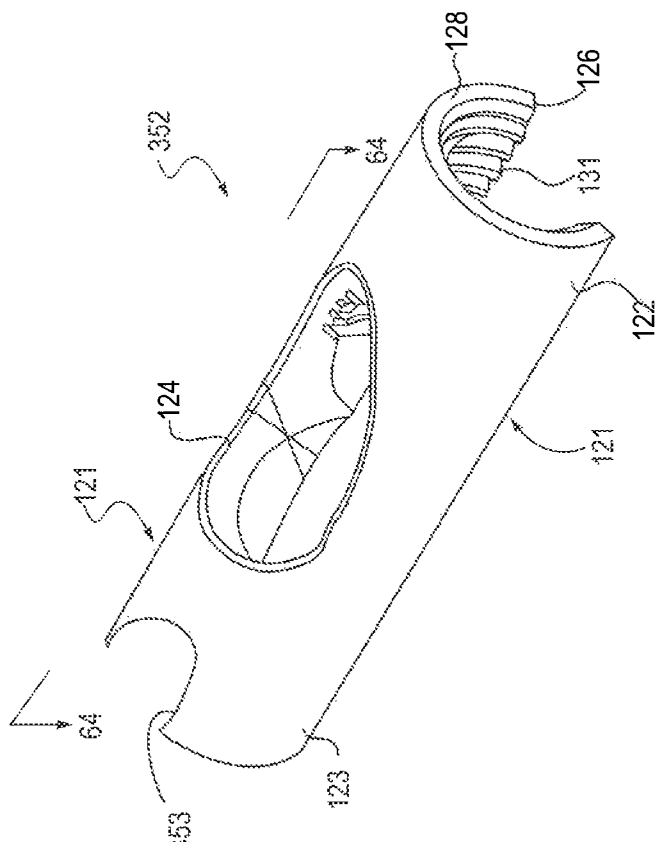
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FIG. 63

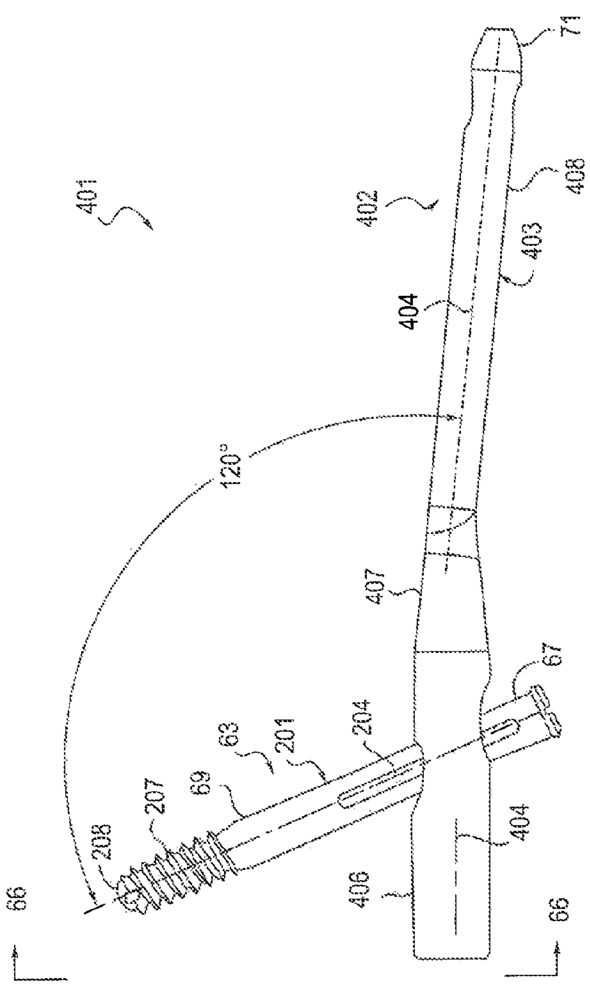


FIG. 65

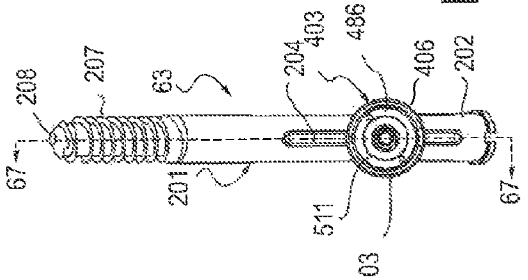


FIG. 66

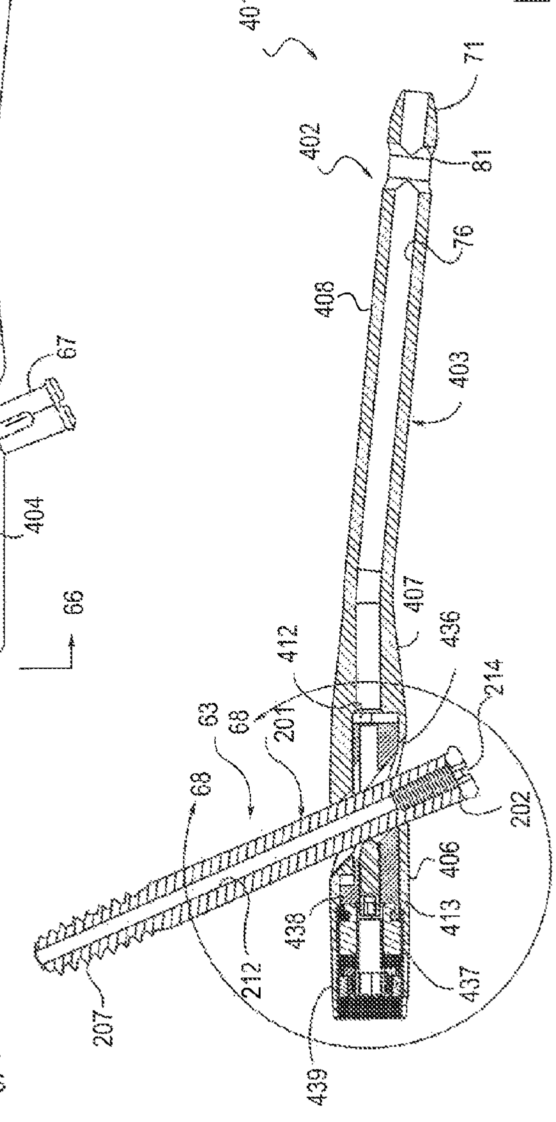
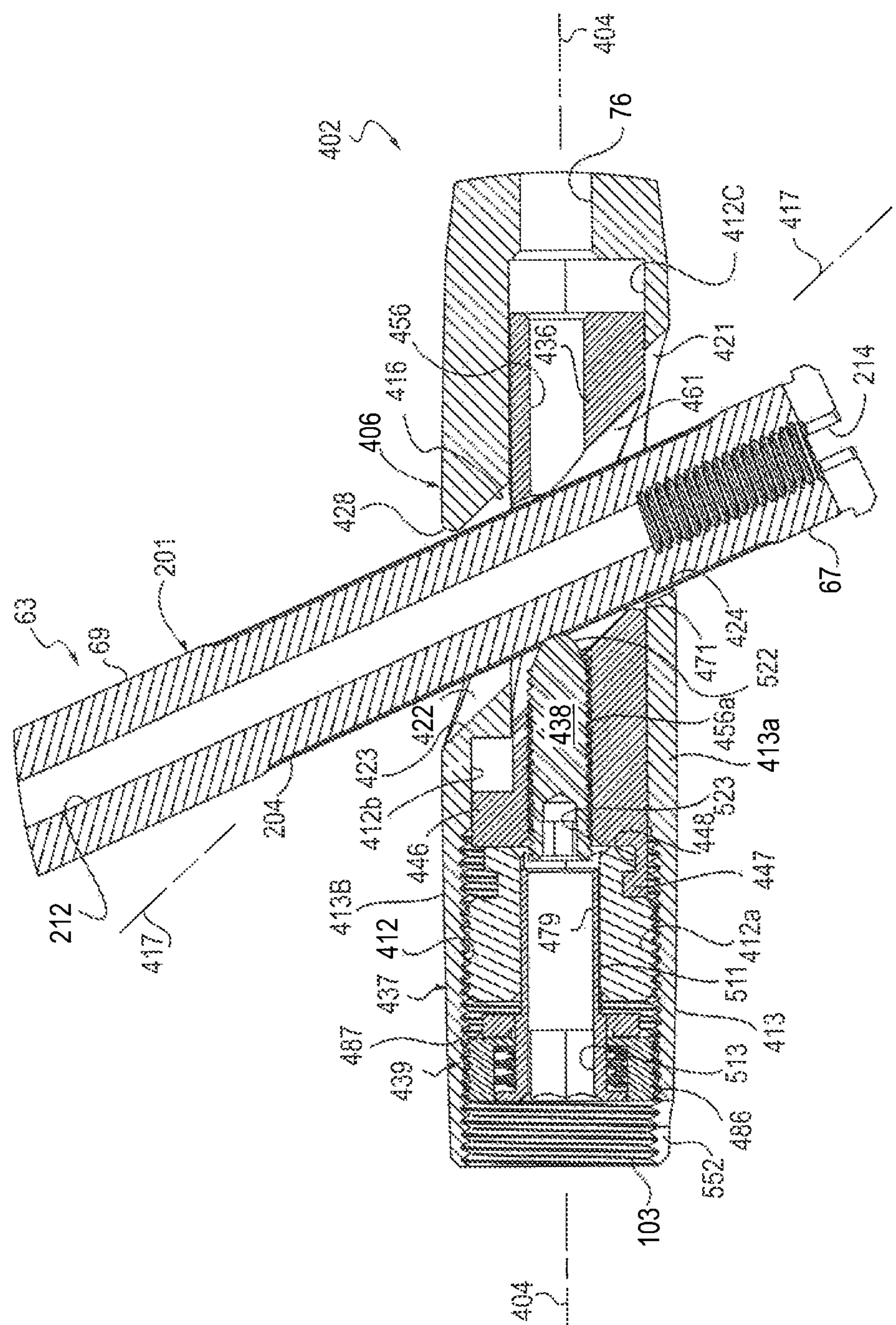


FIG. 67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76
412C
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421
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413a
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412b
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FIG. 68

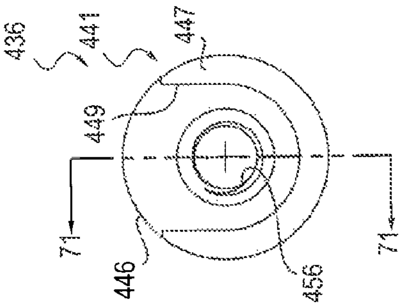

FIG. 70

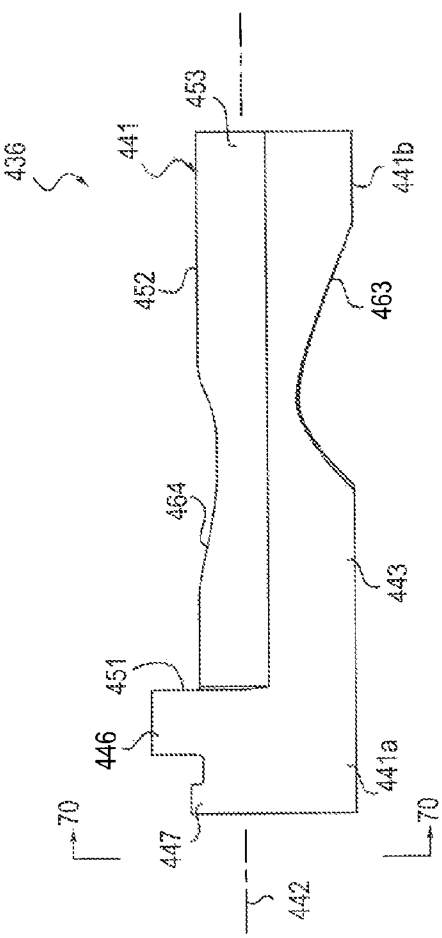

FIG. 69

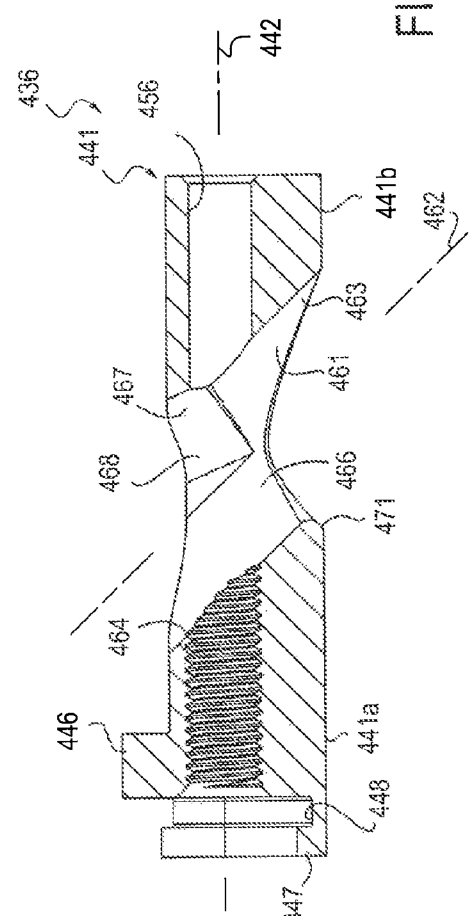

FIG. 71

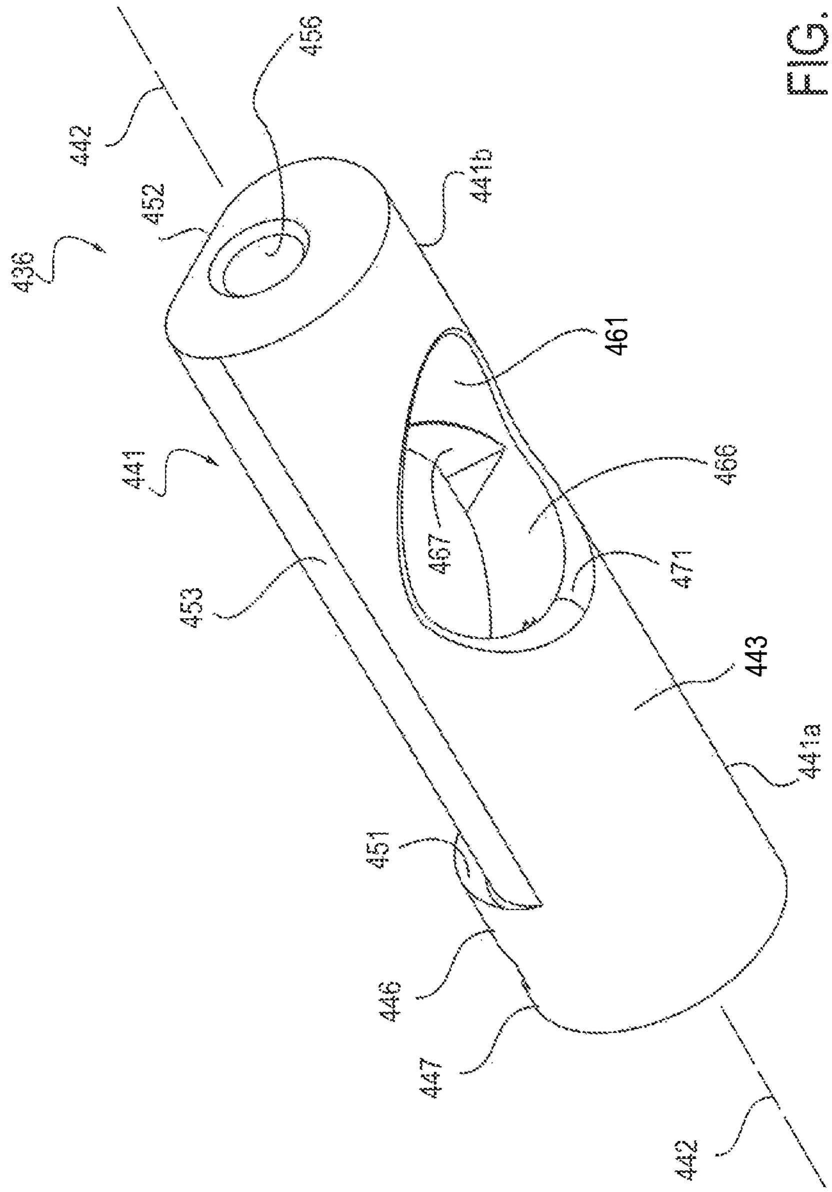
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FIG. 72

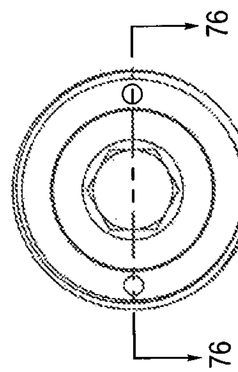

FIG. 75

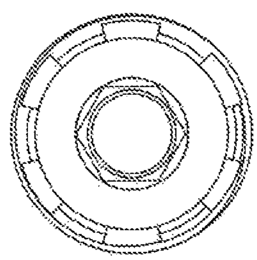

FIG. 74

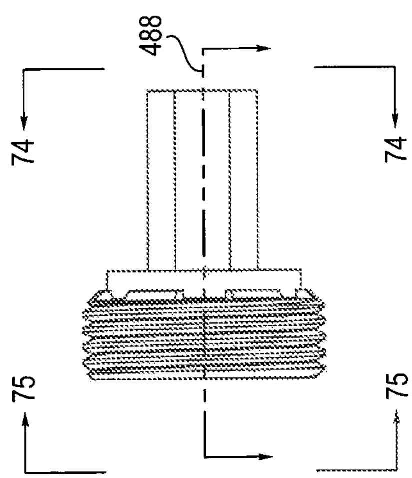

FIG. 73

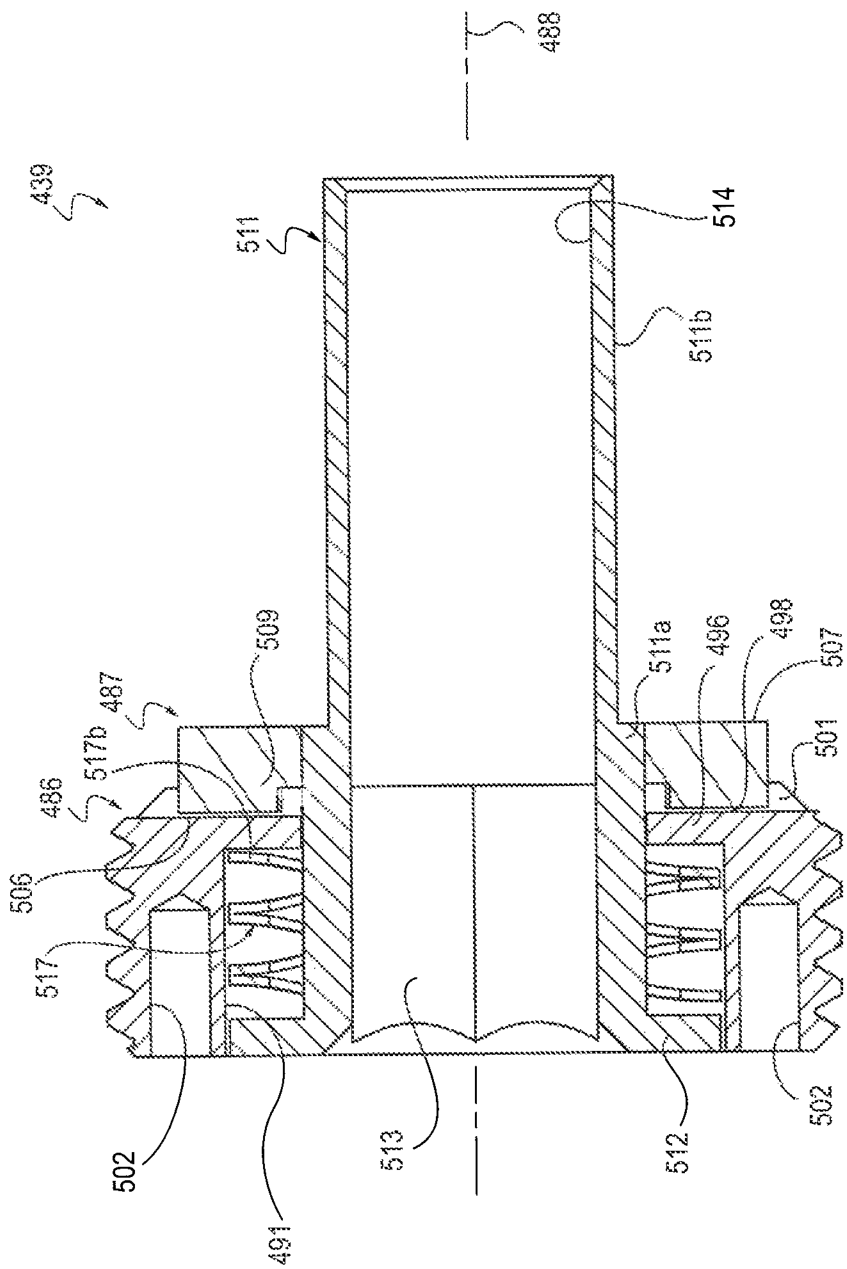
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FIG. 76

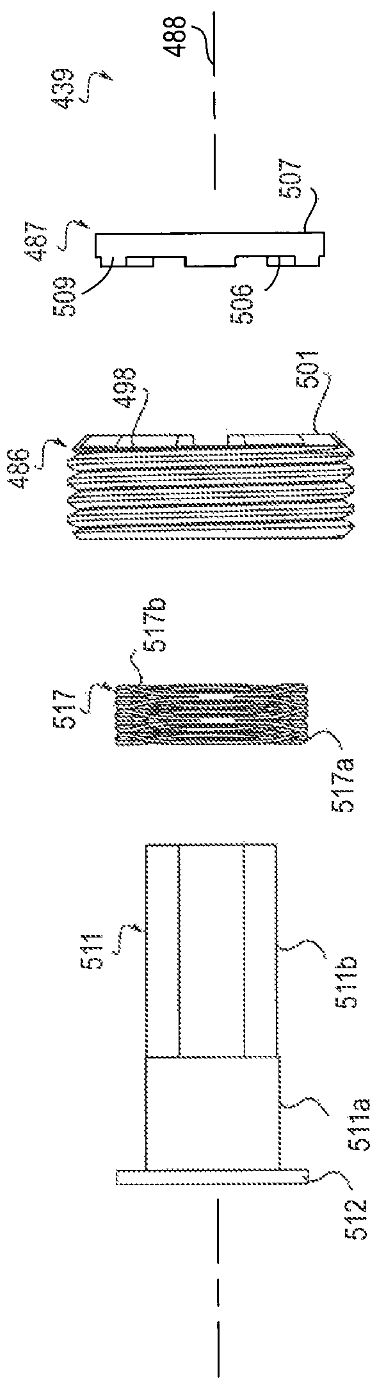

FIG. 77

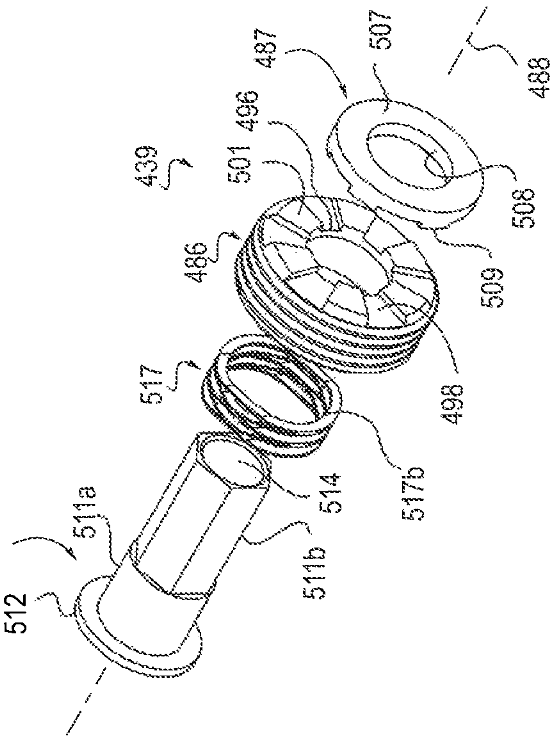

FIG. 79

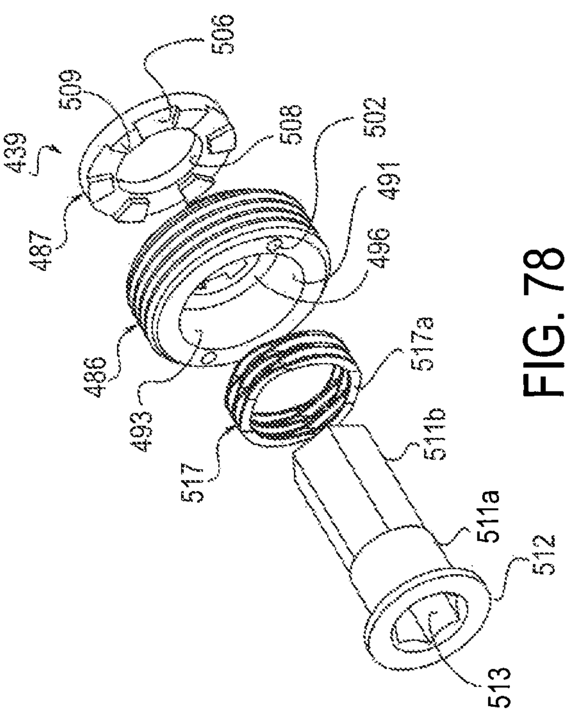

FIG. 78

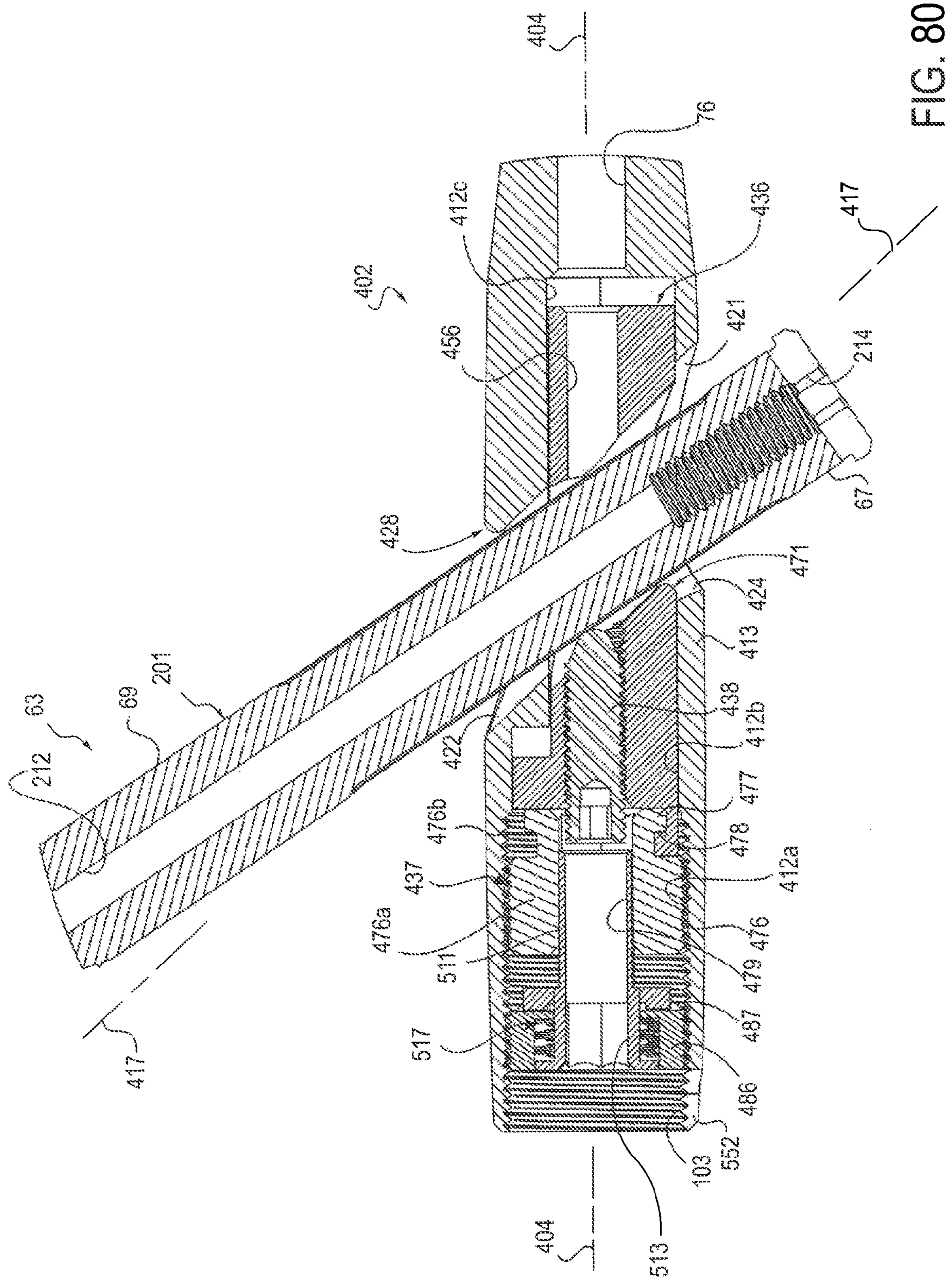
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FIG. 80

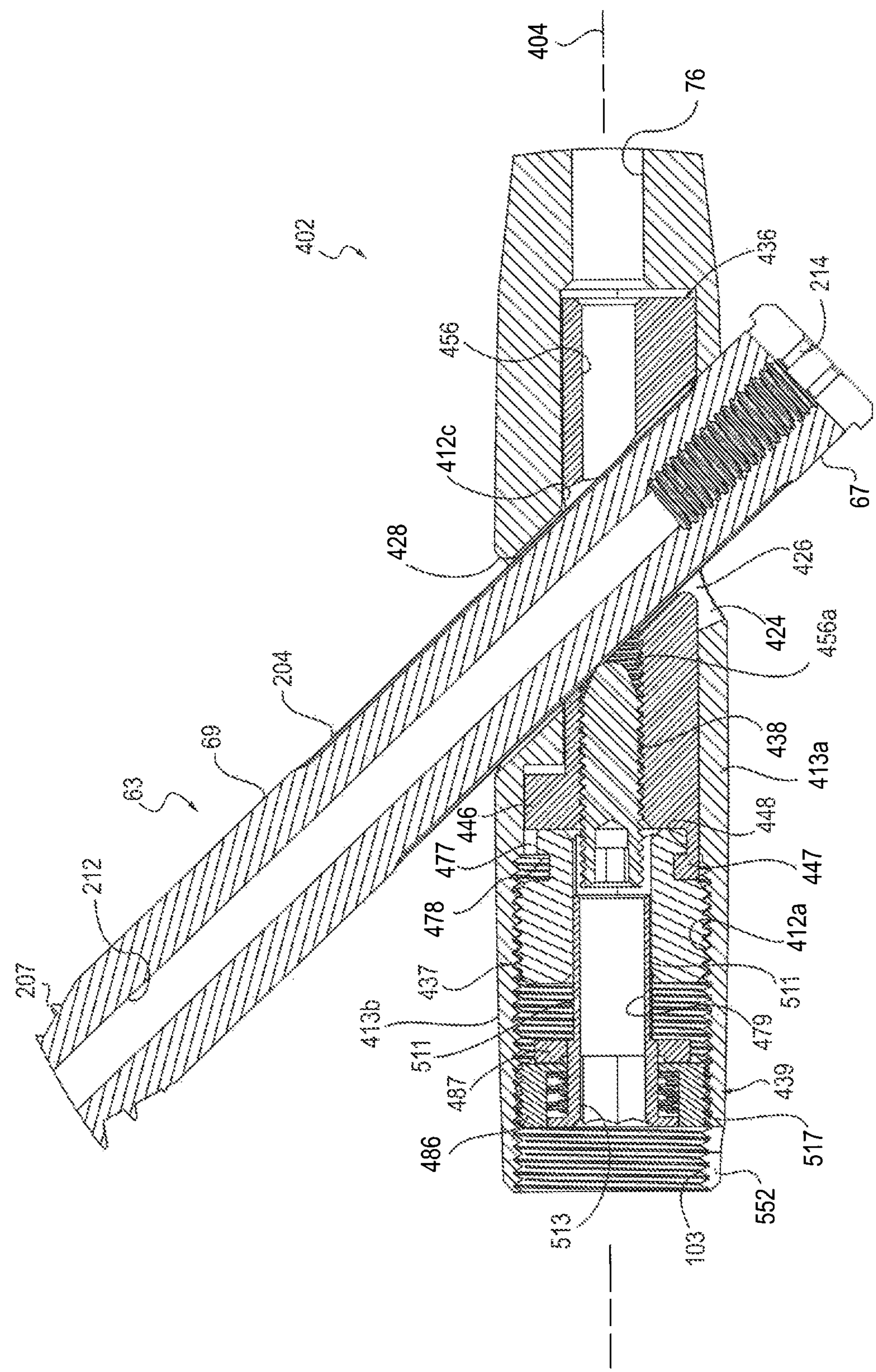
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FIG. 81

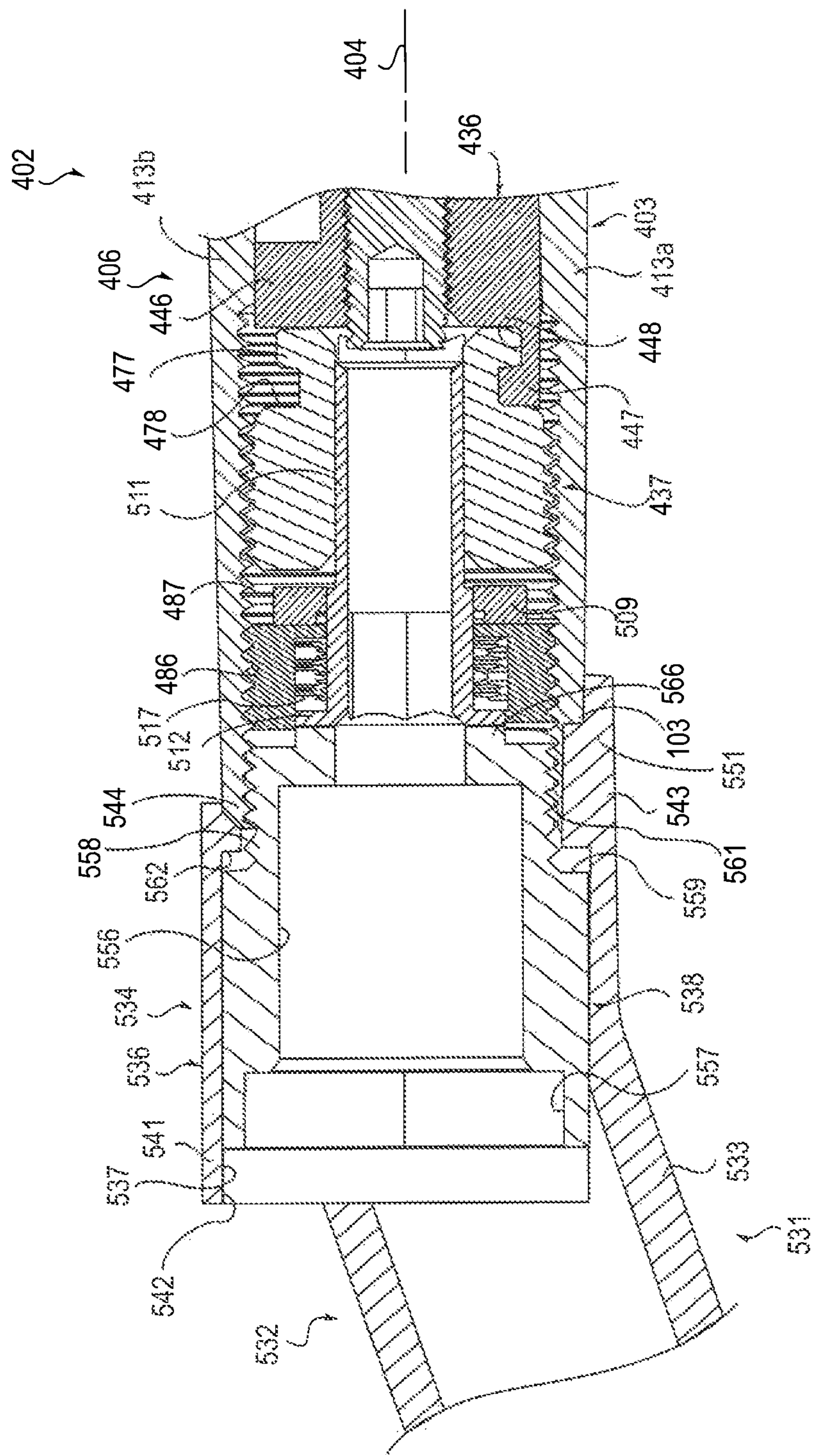
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FIG. 82

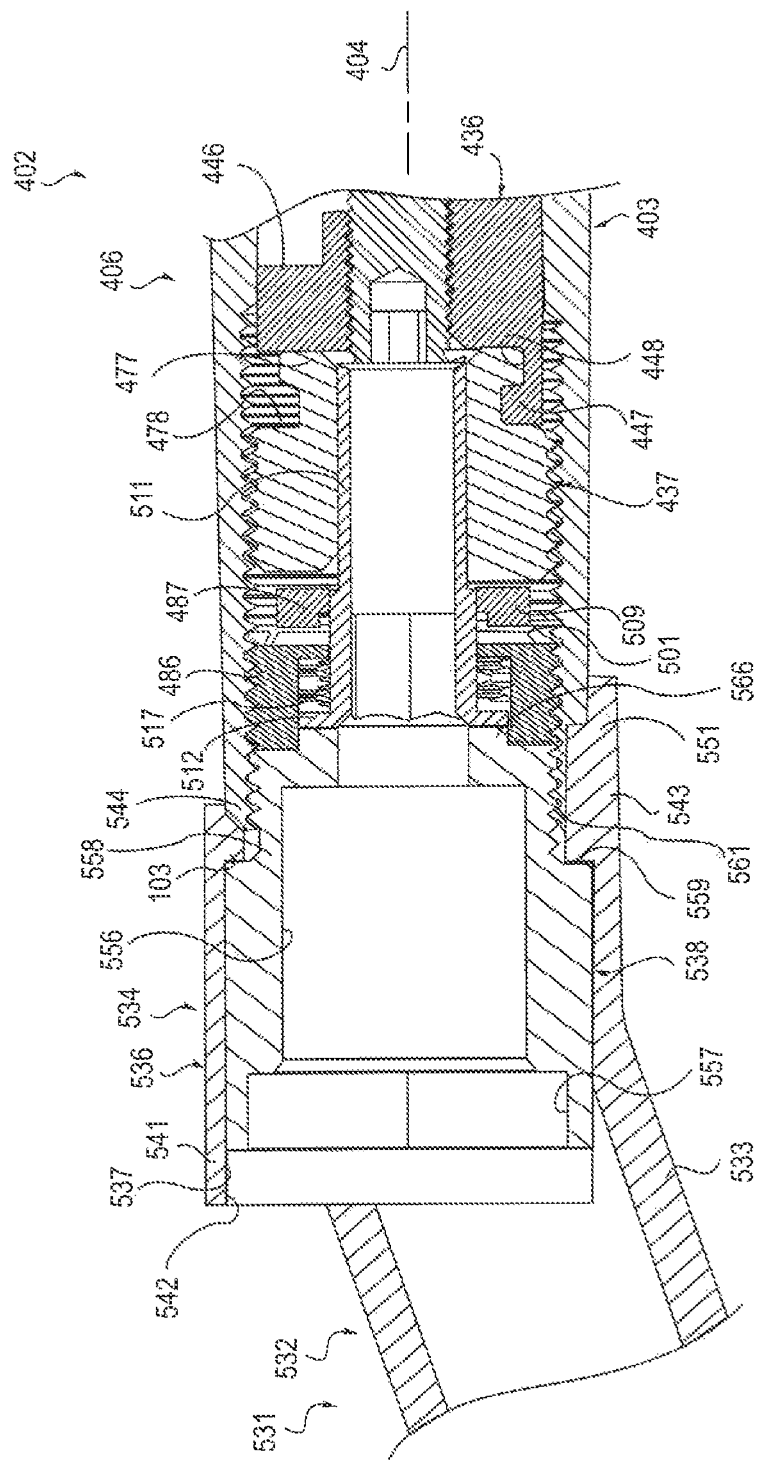
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FIG. 83

IMPLANTABLE DEVICE WITH LOCKING ADJUSTMENT MECHANISM AND METHOD FOR USING SAME

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. provisional patent application Ser. No. 61/576,280 filed Dec. 15, 2011, the entire content of which is incorporated herein by this reference.

FIELD OF THE INVENTION

The present invention relates to apparatus for affixing to bones and, more particularly, to an implantable devices with adjustable members for affixing to bones.

BACKGROUND OF THE INVENTION

There are a variety of devices for affixing to bones. Such devices can include, for example, spinal fasteners, bone plates and intramedullary rods used to treat femoral and other bone fractures. Peritrochanteric fractures of the femur, for example, have been treated with femoral rod assemblies that for example are inserted into the femoral canal to coapt the femur fractured parts. One or two angled cross-nails or locking screws are inserted through the femur and the proximal end of the intramedullary rod.

Currently available nails have been provided with static angled screws that transverse the femoral nail and then achieve adequate fixation strength in the head of the femur. They may also have slots in the nail that allow for dynamic controlled or uncontrolled compression of the fracture site in fractures of the subtrochanteric region and below, either with or without an over sleeve. Frequently, devices that treat femoral neck, intertrochanteric, and subtrochanteric fractures have varying static angles that necessitate an increased inventory to accommodate for varied static angles of the nail.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings described herein are for illustration purposes only and are not intended to limit the scope of the present disclosure in any way.

FIG. **1** is a front view of one embodiment of an intramedullary rod with pivotable fastener of the present invention.

FIG. **2** is a side view of the intramedullary rod with pivotable fastener of FIG. **1** taken along the line **2-2** of FIG. **1**.

FIG. **3** is a rear view, partially sectioned, of the intramedullary rod with pivotable fastener of FIG. **1** taken along the line **3-3** of FIG. **2**.

FIG. **4** is an enlarged cross sectional view of the intramedullary rod with pivotable fastener of FIG. **1** taken along the line **4-4** of FIG. **3**.

FIG. **5** is an exploded view of the head of the intramedullary rod with pivotable fastener of FIG. **1**.

FIG. **6** is a side exploded view of the head of the intramedullary rod with pivotable fastener of FIG. **1** taken along the line **6-6** of FIG. **5**.

FIG. **7** is a front view of the nail of the intramedullary rod with pivotable fastener of FIG. **1** with the components of the actuation mechanism removed.

FIG. **8** is a side view of the nail of FIG. **7** taken along the line **8-8** of FIG. **7**.

FIG. **9** is a cross-sectional view of the nail of FIG. **7** taken along the line **9-9** of FIG. **7**.

FIG. **10** is a cross-sectional view of the proximal portion of the nail of FIG. **7** taken along the line **10-10** of FIG. **8**.

FIG. **11** is a side view of the head of the nail of FIG. **7** taken along the line **11-11** of FIG. **10**.

FIG. **12** is a top end view of the nail of FIG. **7** taken along the line **12-12** of FIG. **11**.

FIG. **13** is a cross-sectional view of the proximal portion of the nail of FIG. **7** taken along the line **13-13** of FIG. **12**.

FIG. **14** is a perspective view of the insert of the intramedullary rod with pivotable fastener of FIG. **1**.

FIG. **15** is a top view of the insert of FIG. **14** taken along the line **15-15** of FIG. **14**.

FIG. **16** is an end view of the insert of FIG. **14** taken along the line **16-16** of FIG. **15**.

FIG. **17** is a cross-sectional view of the insert of FIG. **14** taken along the line **17-17** of FIG. **16**.

FIG. **18** is a perspective view of the end nut of the intramedullary rod with pivotable fastener of FIG. **1**.

FIG. **19** is a side view of the end nut of FIG. **18** taken along the line **19-19** of FIG. **18**.

FIG. **20** is bottom end view of the end nut of FIG. **18** taken along the line **20-20** of FIG. **18**.

FIG. **21** is top end view of the end nut of FIG. **18** taken along the line **21-21** of FIG. **19**.

FIG. **22** is a cross-sectional view of the end nut of FIG. **18** taken along the line **22-22** of FIG. **21**.

FIG. **23** is a perspective view of the spindle of the intramedullary rod with pivotable fastener of FIG. **1**.

FIG. **24** is a side view of the spindle of FIG. **23** taken along the line **24-24** of FIG. **23**.

FIG. **25** is top end view of the spindle of FIG. **23** taken along the line **25-25** of FIG. **24**.

FIG. **26** is bottom end view of the spindle of FIG. **23** taken along the line **26-26** of FIG. **24**.

FIG. **27** is a cross-sectional view of the spindle of FIG. **23** taken along the line **27-27** of FIG. **25**.

FIG. **28** is a perspective view of the set screw of the intramedullary rod with fastener of FIG. **1**.

FIG. **29** is a side view of the set screw of FIG. **28** taken along the line **29-29** of FIG. **28**.

FIG. **30** is an end view of the set screw of FIG. **28** taken along the line **30-30** of FIG. **29**.

FIG. **31** is a cross-sectional view of the set screw of FIG. **28** taken along the line **31-31** of FIG. **30**.

FIG. **32** is a perspective view of the fastener of the intramedullary rod with fastener of FIG. **1**.

FIG. **33** is a side view of the fastener of FIG. **32** taken along the line **33-33** of FIG. **32**.

FIG. **34** is an end view of the fastener of FIG. **32** taken along the line **34-34** of FIG. **33**.

FIG. **35** is a cross-sectional view of the fastener of FIG. **32** taken along the line **35-35** of FIG. **34**.

FIG. **36** is a front view of the proximal portion of the intramedullary rod with pivotable fastener of FIG. **1** showing the fastener in the first position of FIG. **1** relative to the intramedullary rod and the fastener in a second position relative pivoted counterclockwise to the intramedullary rod.

FIG. **37** is a cross-sectional view of the proximal portion of the intramedullary rod and pivotable fastener of FIG. **1** showing the fastener in a third position relative to the intramedullary rod.

FIG. **38** is a front view of another embodiment of an intramedullary rod with pivotable fasteners of the present invention.

FIG. **39** is a side view of the intramedullary rod with pivotable fasteners of FIG. **38** taken along the line **39-39** of FIG. **38**.

FIG. **40** is a cross-sectional view of the intramedullary rod with pivotable fasteners of FIG. **38** taken along the line **40-40** of FIG. **39**.

FIG. **41** is a perspective view of the insert of the intramedullary rod with pivotable fasteners of FIG. **38**.

FIG. **42** is a top view of the insert of FIG. **41** taken along the line **42-42** of FIG. **41**.

FIG. **43** is an end view of the insert of FIG. **41** taken along the line **43-43** of FIG. **42**.

FIG. **44** is a cross-sectional view of the insert of FIG. **41** taken along the line **44-44** of FIG. **43**.

FIG. **45** is a perspective view of the spindle of the intramedullary rod with pivotable fasteners of FIG. **38**.

FIG. **46** is a side view of the spindle of FIG. **45** taken along the line **46-46** of FIG. **45**.

FIG. **47** is an end view of the spindle of FIG. **45** taken along the line **47-47** of FIG. **46**.

FIG. **48** is a cross-sectional view of the spindle of FIG. **45** taken along the line **48-48** of FIG. **47**.

FIG. **49** is a side view of the set screw of the intramedullary rod with pivotable fasteners of FIG. **38**.

FIG. **50** is an end view of the set screw of FIG. **49** taken along the line **50-50** of FIG. **49**.

FIG. **51** is a cross-sectional view of the set screw of FIG. **49** taken along the line **51-51** of FIG. **50**.

FIG. **52** is a perspective view of the set screw of FIG. **49** mounted on the spindle of FIG. **45**.

FIG. **53** is a front view of a distal portion of a further embodiment of an intramedullary rod with pivotable fasteners of the present invention.

FIG. **54** is a front view of a distal portion of a yet another embodiment of an intramedullary rod with pivotable fasteners of the present invention.

FIG. **55** is a side view of a distal portion of a yet a further embodiment of an intramedullary rod with pivotable fasteners of the present invention.

FIG. **56** is an end view of the intramedullary rod with pivotable fastener of FIG. **55** taken along the line **56-56** of FIG. **55**.

FIG. **57** is a schematic front view of the intramedullary rod with pivotable fasteners of FIG. **38** disposed in a femur to repair a femoral neck fracture.

FIG. **58** is a schematic front view of the intramedullary rod with pivotable fasteners of FIG. **38** disposed in a femur to repair an intertrochanteric fracture.

FIG. **59** is a schematic front view of the intramedullary rod with pivotable fasteners of FIG. **38** disposed in a femur to repair a subtrochanteric fracture.

FIG. **60** is a front view an embodiment of an intramedullary rod with pivotable and fixed fasteners of the present invention.

FIG. **61** is a side view of the intramedullary rod with pivotable and fixed fasteners of FIG. **60** taken along the line **61-61** of FIG. **60**.

FIG. **62** is an enlarged cross sectional view of the intramedullary rod with pivotable and fixed fasteners of FIG. **60** taken along the line **62-62** of FIG. **61** and including another embodiment of the fixed fastener.

FIG. **63** is a top view, similar to FIG. **15**, of the insert of the intramedullary rod with pivotable and fixed fasteners of FIG. **60**.

FIG. **64** is an end view of the insert of FIG. **63** taken along the line **64-64** of FIG. **63**.

FIG. **65** is a rear view of a further embodiment of an intramedullary rod with pivotable fastener of the present invention.

FIG. **66** is a top end view of the intramedullary rod with pivotable fastener of FIG. **65** taken along the line **66-66** of FIG. **65**.

FIG. **67** is a cross-sectional view of the intramedullary rod with pivotable fastener of FIG. **65** taken along the line **67-67** of FIG. **66**.

FIG. **68** is an enlarged cross sectional view of the intramedullary rod with pivotable fastener of FIG. **65** taken along the line **68-68** of FIG. **67**.

FIG. **69** is a side view of the insert of the intramedullary rod with pivotable fastener of FIG. **65**.

FIG. **70** is a top end view of the insert of FIG. **69** taken along the line **70-70** of FIG. **69**.

FIG. **71** is a cross-sectional view of the insert of FIG. **69** taken along the line **71-71** of FIG. **70**.

FIG. **72** is a perspective view of the insert of FIG. **69**.

FIG. **73** is a side view of the, locking mechanism of the intramedullary rod with pivotable fastener of FIG. **65**.

FIG. **74** is a bottom end view of the locking mechanism of FIG. **73** taken along the line **74-74** of FIG. **73**.

FIG. **75** is a top end view of the locking mechanism of FIG. **73** taken along the line **75-75** of FIG. **73**.

FIG. **76** is a cross-sectional view of the locking mechanism of FIG. **73** taken along the line **76-76** of FIG. **75**.

FIG. **77** is a side exploded view of the locking mechanism of FIG. **73**.

FIG. **78** is a first perspective view of the exploded locking mechanism of FIG. **73**.

FIG. **79** is a second perspective view of the exploded locking mechanism of FIG. **73**.

FIG. **80** is an enlarged cross sectional view, similar to FIG. **68**, of the intramedullary rod of FIG. **65** with the pivotable fastener in a second position.

FIG. **81** is an enlarged cross sectional view, similar to FIG. **68**, of the intramedullary rod of FIG. **65** with the pivotable fastener in a third position.

FIG. **82** is an enlarged cross-sectional view of a portion of intramedullary rod of FIG. **68** coupled to a connector of a targeting assembly with the locking mechanism in a first position.

FIG. **83** is a cross-sectional view, similar to FIG. **82**, with the locking mechanism in a second position.

DETAILED DESCRIPTION OF THE INVENTION

In general, an apparatus or device is provided for treating fractures, nonunions or malunions of the femur or other bones of a mammalian body and includes an intramedullary rod or nail and at least one fastener carried by the rod. At least one opening is provided in the head of the apparatus for slidably receiving the one or more fasteners and permitting the fastener or fasteners to pivot relative to the head of the apparatus.

In one preferred embodiment, the apparatus **61** of the invention comprises an intramedullary rod **62** and a proximal fastener **63** pivotably carried by the proximal portion of the rod (see FIGS. **1-3**). The proximal fastener **63** can be of any suitable type, including a fixation screw, a screw, a peg, a helical blade or any other fixation device, and for simplicity is referred to herein as a fixation screw. The femoral nail or rod **62** includes an elongate body **64** that extends along a longitudinal axis **66** and can have a proximal portion or head **67**, a central portion or neck **68** and a distal portion or shaft **69** that terminates at a distal tip **71**. The elongate body **64** may curve in at least one portion of the shaft or stem **69** to align the rod **62** along the length of the marrow canal of the femur when the rod is inserted in the femur. The elongate body **64** can be made from any suitable material such as stainless steel, titanium or another alloy and can have a length, dependent in part on the length in which the rod **62** is to be utilized, ranging from 180 to 500 centimeters. The head **67** of the nail **62** can have a length ranging from four to 15 centimeters and preferably ranging from eight to 12 centimeters and a diameter ranging from eight to 20 millimeters.

A longitudinally-extending passageway or bore **76**, shown in part in FIGS. **3-4** and **9-10**, can be provided and extends from a proximal opening **77** in the head **67** to an opening **78** in the tip of the stem for permitting the rod to slide along a guide wire during insertion of the rod into the femur. The curve of the longitudinal axis **66**, and thus the curve of the stern **69** of the rod **62**, can be through a single plane or through multiple planes. In the illustrated embodiment of nail **62**, as shown in FIGS. **8**, **10**, **12** and **13**, the curve of body **64** extends through multiple planes. At least one and in one embodiment first and second bores **81**, which can extend perpendicular to the longitudinal axis **66**, are provided in the distal end portion of the stern **69** adjacent the tapered tip **71** of the stem. The bores are sized to receive respective distal fasteners, such as fixation screws, screws, pegs, helical blades or any other suitable fixation devices, and in one embodiment such distal fasteners are in the form of fixation screws or screws **82** that can be fixed at an orthogonal angle relative to stem **69**. In the illustrated embodiment and as shown in FIGS. **1-2** and **7-9**, the distal-most bore **81** is elongated in its transverse direction, that is parallel to the longitudinal axis **66** of the stem **69**, to permit the stem to be moved longitudinally relative to the respective distal fastener or fixation screw **82** before tightening of the fastener or screw to the underlying portion of the femur.

At least one transverse apertures or opening **91** is provided through the head **67** of the rod **62** and in one embodiment is angled toward the proximal end of the rod relative to longitudinal axis **66** for receiving the proximal fixation screw or fixation screw **63**. More specifically, the one or more transverse apertures or holes **91** each pivotably receive a fixation screw **63** and allow for changing the angle made between the screw **63** and the nail **62**. Each such aperture or first hole can extend through the head **67** in an angled direction relative to longitudinal axis **66** such that when the rod is in position within the marrow canal of the femur, axis **92** of the opening is directed toward the head of the femur (see FIG. **13**). As can be seen from FIGS. **5**, **6** and **10-13**, the transverse aperture or aperture **92** in the head **67** can communicate with a first or lateral transverse opening **93**, through which the respective fixation screw is inserted, and an opposite second or medial transverse opening **94**, from which the distal portion of the screw extends. The medial transverse opening **94**, as shown in FIGS. **5**, **8**, **11** and **13**, can be elongate or oblong in a transverse direction that is parallel to longitudinal axis **66** of head **67** and body **64**, so as to accommodate pivoting of the distal portion of the proximal fixation screw **63**.

The head **67** of rod **62** may include an actuation or adjustment mechanism or assembly **101** for selectively pivoting the proximal fixation screw **63** within the transverse aperture **91** (see FIGS. **4-31**). In this regard, the proximal portion of the central passageway **76** of the nail **62** can be hollowed to form a longitudinally-extending proximal recess **102** in the head that communicates with a proximal opening **103** in the head. As illustrated in FIGS. **12** and **13**, the recess **102** can have a proximal portion **102***a*, adjacent the proximal opening **103**, and a segmented circular portion **102***b* that extends in cross section through any suitable angle preferably ranging from 180 to 240 degrees and illustrated in FIG. **12** as approximately 240 degrees, along the inside of the head **67** adjacent the medial transverse opening **94**. Internal threads **104** can be provided in proximal portion **102***a*. The segmented circular portion or segmented portion **102***b* of recess **102** may be formed from an inner arcuate surface **105**. The other side of the recess **102**, that is the side opposite of segmented portion **102***b*, can be formed with a first shelf **107**, a second shelf **108** and a third shelf **109** that can each extend further radially inwardly than the inner arcuate surface **105** of the segmented portion **102***b* and can have increasingly smaller radii relative to longitudinal axis **66** (see FIGS. **11-13**). The proximal portion of the first shelf **107** can be optionally provided with internal threads **111**, as shown in FIGS. **4**, **9** and **10**. A shoulder **112** can extend radially inwardly from first shelf **107** to second shelf **108** (see FIG. **13**). The third shelf **109** may abut the lateral transverse opening **93**, as shown in FIG. **11**. Transversely aligned slots **110** may be provided on the proximal end of head **67** at proximal opening **103** for registering the nail **62** with an insertion jig, targeting device or other suitable device when placing or otherwise manipulating the nail within the targeted bone.

Although the actuation or adjustment mechanism **101** for pivoting the proximal fixation screw **63** can be of any suitable type, in one embodiment the mechanism **101** includes an insert or sleeve **116**, a control element **117**, an end or safety nut **118** and an alignment or set screw **119**, as shown in the exploded views of FIGS. **5-6** and in the assembled view of FIG. **4**. Each of these components can be made from any suitable material such as stainless steel.

Elongate insert or sleeve **116**, as illustrated in FIGS. **14-17**, may be formed from a tubular-like member **121** that can have a proximal portion **122** and a distal portion **123** and a longitudinally-extending opening **124** extending through one side. Sleeve **116** can have the shape of a cylinder with an elongate cutout **126** provided along one side thereof, opposite opening **124**, that communicates with the longitudinal bore **127** extending therethrough from proximal or top end **128** and distal or bottom end **129**. The planar top and bottom ends can extend parallel to each other. As such, sleeve **116** has a segmented circular or C shape when viewed from an end along its longitudinal axis, as shown in FIG. **16**. Such transverse, cross-sectional configuration of sleeve **116** preferably approximates the cross-sectional configuration of the segmented circular portion **102***b* of the recess **102** in head **67** and can extend through an arc ranging from 100 to 360 degrees, preferably ranging from 180 to 240 degrees and illustrated in FIG. **16** as approximately 240 degrees. The elongate transverse opening **124** can be formed in the center of the insert. Such opening **124** may be oblong or elongate in shape and smaller than the medial transverse opening **94** provided in head **67** of the nail **62**. The insert **116** may be provided with internal thread **131** extending through the bore **127** at the proximal portion **122** of the insert, such threads being adjacent the top or proximal end of the insert as shown in FIGS. **14** and **17**. The insert can have a length ranging from 30 to 110 millimeters and can have an external radius sized to fit within head **67** of the nail **62**. The distal portion of internal bore **127** that is the portion of the bore distal transverse opening **124**, has a smaller internal diameter than the internal diameter of the proximal portion of the bore.

Control element **117** can be of any suitable type and in one embodiment includes a spindle or screw **117** formed from a cylindrical body **136** provided with a distal portion **137** of constant radius and can have a smooth outer cylindrical surface **138**, a central portion **139** adjacent the distal portion and having external threads **141** extending radially outwardly relative to the distal portion and a proximal or neck portion **142** adjacent the central portion (see FIGS. **18-22**). The neck portion can include a proximal flange **143** and an annular recess **144** disposed between the flange and the central portion **139** of the spindle or screw **117**. The cylindrical body can further include a proximal or top end **147** and a distal or bottom end **148**, as shown in FIG. **22**. The planar ends **148** and **148** may extend parallel to each other. A central passageway or bore **151** can extend through the spindle. The distal portion of the central passageway may be provided with internal thread **152** and the proximal portion of the central passageway may be provided with any suitable cross-sectional configuration for serving as a drive socket **153**. The spindle can have a length ranging from five to 50 millimeters and preferably approximately 15 millimeters.

End nut **118** can be formed from a cylindrical body **161** provided with a distal portion **162** of constant radius and a smooth outer surface **163** and a proximal portion **164** adjacent the distal portion and having external threads **166** extending radially outwardly relative to the distal portion (see FIGS. **23-27**). The cylindrical body can further include a proximal or top end **167** and a distal or bottom end **168**, as shown in FIG. **27**. Planar ends **167** and **168** can extend parallel to each other. A central passageway or bore **171** can extend longitudinally through the end nut between ends **167** and **168** and at least the proximal portion of the bore **171** can be provided with any suitable cross-sectional configuration for serving as a drive socket. The distal end portion of the end nut may be provided with a recess or socket **172** that can be in communication with bore **171** and be side opening onto the outer cylindrical surface **163** of the distal portion **162**. The socket **172** can be sized and configured for cooperatively receiving the neck portion **142** of the spindle **117** and may include a partial annular flange **173**, shown most clearly in FIG. **24**, extending radially inwardly for partially seating in the annular recess **144** of the spindle and a partial annular recess **174** extending radially outwardly relative to the flange for receiving part of the proximal, annular flange **143** of the spindle. The end nut can have a length ranging from five to 50 millimeters and preferably approximately 15 millimeters.

Set screw **119** can be formed from a cylindrical body **181** provided with a distal portion **182** of constant radius and a smooth outer surface **183** and a proximal portion **184** adjacent the distal portion and having external threads **186** extending radially outwardly relative to the distal portion (see FIGS. **28-31**). The cylindrical body **181** can further include a proximal or top end **187** and a distal or bottom end **188**, as shown in FIG. **29**. A drive socket **191** of any suitable cross-sectional configuration may extend longitudinally through at least a portion of the cylindrical body and open at the top end **187** of the body. The bottom end **188** of the body can be blunted. The set screw can have a length ranging from five to 60 millimeters and preferably approximately 20 millimeters.

Proximal fastener **63** for use in the head **67** of the intramedullary rod **62** can be of any suitable type and in one embodiment is made from an elongate cylindrical body **201** or spiral blade (not shown) having a length ranging from 40 to 200 millimeters and a diameter ranging from two to 20 millimeters (see FIGS. **32-35**). In the illustrated embodiment, the fastener is a fixation screw formed from a body having a threaded portion and a smooth portion. The elongate body **201** can be formed from any suitable material such as stainless steel and include a proximal portion **202** having any outer cylindrical or irregular-shaped surface **203**. The proximal portion **202** may be provided with a plurality and as shown four longitudinally-extending slots **204** extending through the surface **203** in circumferentially-spaced apart positions. Distal portion **206** of the body **201** may be provided with external threads **207** that extend to a sharpened distal end or tip **208** of the body. Alternatively, the distal portion **206** of the body **207** may be irregularly shaped or flat (not shown). The body can further have a proximal end **211** and be provided with a central bore **212** that extends longitudinally through the body from the proximal end **211** to the distal end **208** (see FIG. **35**). The proximal end of the central bore **212** may be provided with internal threads **213** and be formed with a drive socket **214** of any suitable type for facilitating connection of the proximal fixation screw to a drive tool of any suitable type.

Actuation assembly or mechanism **101** loaded into the head **67** of the nail **62** in any suitable manner. In one method of assembly, insert or sleeve **116** is slidably inserted through the proximal opening **103** of the head and slidably seated in the segmented circular portion **102***b* of the recess **102** in the head. The transverse opening **124** in the insert **116** is in general registration with the medial transverse opening **94** in the head **67**. The proximal or neck portion **142** of spindle **117** is seated in the socket **172** formed in the distal portion **162** of end nut **118** so that the end nut and spindle are coaxial along the central longitudinal axes of the end nut and spindle. The combined spindle **117** and end nut **118** assembly are loaded into the head **67** by introducing the distal portion **137** of the spindle into the proximal opening **103** in the head. A suitable drive tool (not shown) can be used to engage the drive socket in the central bore **171** at the proximal portion **164** of the end nut to rotate the end nut within the internal threads **104** adjacent the proximal opening **103** in the head so as to move the end nut **118**, and the spindle **117** captured thereby, longitudinally into the recess **102** of the head until the spindle seats is the distal portion of the first shelf **107** against shoulder **112** extending between the first shelf **107** and the second shelf **108**. As spindle **117** is moved distally within the recess **102** of the head **67**, the external threads **141** of the spindle engage the internal threads **131** on the proximal portion **122** of insert **116**. The spindle can be moved longitudinally into threaded engagement with the insert by engagement of the drive socket **153** in the proximal or neck portion **142** of spindle **117** with a suitable drive tool and clockwise rotation of the spindle within the recess **102** of the head **67**.

The set screw **119** can thereafter be introduced through central bore **171** of the end nut **118** and into central bore **151** of the spindle **117** until the external threads **186** provided on the proximal end portion **184** of the set screw engage the internal threads **152** provided within the distal portion **137** of the spindle. A suitable drive tool may be used to engage the drive socket **191** in the proximal portion **184** of the set screw **119** to move the set screw distally relative to the spindle **117** by the rotational engagement of the external threads **186** on the set screw with the internal threads **152** of the spindle. The distal portion **182** of the set screw can thus be moved distally of the spindle **117** into the transverse aperture **91** in head **67** of the nail **62**.

Upon insertion of the proximal fixation screw **63** into the transverse aperture **91** of the head **67**, and through the transverse opening **124** in the insert **116**, the fixation screw can be pivoted about a transverse axis of the head through an angle of up to 70 degrees and preferably approximately 30 degrees relative to the nail **62**. In one embodiment, illustrated in the figures, the fixation screw **63** is pivotable between a first position **216**, extending at an angle α of approximately 115 degrees relative to the stem **69** of the nail and shown in FIG. **36**, and a second position **217**, extending at an angle α of approximately 145 degrees relative to the stem of the nail and shown in FIG. **37**. The fixation screw is shown in an intermediate position **218**, extending at an angle α of approximately 130 degrees relative to the stem of the nail, in FIG. **36**. To so pivot the fixation screw, in one procedure the physician rotates the spindle **117** within the head **67**, for example by engaging the drive socket **153** in the neck portion **142** of the spindle with a suitable drive tool, so that the external threads **141** on the central portion **139** of the spindle that engage the internal threads **131** within the insert **116** cause the insert to move proximally within the head from a first or distal position in the segmented circular portion (not shown) to a second or proximal position in the segmented circular portion, illustrated in FIG. **37**. The distal end of the transverse opening **124** in the insert **116** engages the fixation screw during proximal movement of the insert within the head **67** to cause the fixation screw to pivot within the medial transverse opening **93** of the transverse aperture **91** of the head. When in its operational position within the head **67**, shown in FIG. **37**, the spindle **117** can rotate freely relative to the head and the end cap **118**. The set screw **119** can be rotated distally with the spindle **117** so that the blunted end **188** of the set screw seats within one of the longitudinal slots **294** formed in the proximal portion **202** of the fixation screw **63** so as to rotatably lock the fixation screw relative to the head **67** of the intramedullary rod **62** and thus inhibit undesirable further advancement or withdrawal of the screw **63** relative to the rod **62**.

Although the actuation mechanism **101** of intramedullary rod **62** has been shown and described with a longitudinally movable insert or sleeve **116** disposed within the nail, it is appreciated that an insert or sleeve slidably disposed on the outside of the nail **62** can be provided for pivoting the fixation screw **62** relative to the nail.

It is further appreciated that other embodiments of the intramedullary rod of the present invention, for example with any plurality of pivotable fasteners can be provided. Another apparatus **231** is illustrated in FIGS. **38-52** and can include an intramedullary rod **232** substantially similar to rod **62**. Like reference numerals have been utilized to describe like components of rods **62** and **232**. The intramedullary rod **232** has any suitable first and second proximal fasteners, shown as first and second proximal fixation screws **233** and **234** that can each be substantially identical to proximal fixation screw **63**, pivotably received within respective first and second transverse apertures **236** and **237** that can each be substantially identical to transverse aperture **91** and extend along respective axes **92**. The first and second fasteners **233** and **234** extend parallel to each other, may or may not be of the same length and may or may not be of the same type of fastener. For example, the first fastener **233** may be a screw and the second fastener **234** may be a peg or blade. The apertures **236** and **237** are provided in a head **239**, substantially similar to head **67**, of the rod **232**.

An actuation mechanism or assembly **241**, substantially similar to actuation mechanism **101**, can be provided with the head **239** of the rod **232**. Actuation mechanism **241**, shown in an assembled position in FIG. **40**, can include an insert or sleeve **242** substantially similar to the insert **116** of mechanism **101** but having first and second transverse apertures **246** and **247** similar to transverse aperture **91** of the sleeve **116** and extending at an angle to the longitudinal axis of the nail for respectively receiving and pivoting the first and second fixation screws **233** and **234** (see FIGS. **41-44**). The axes **92** of the first and second transverse apertures **246** and **247** can be parallel to each other but may also not be parallel to each other. The insert **242** can have a length ranging from 20 to 120 millimeters and an external radius sized to fit within head **239** of the nail **232**. A spindle **256** can be provided that is substantially similar to the spindle **117** but formed without the distal portion **137** of spindle **117** (see FIGS. **45-48**). Instead, spindle **256** of the dual fixation screw rod **232** of FIGS. **38-52** has a proximal or neck portion **142** and a distal portion **257** substantially similar to central portion **139** of the spindle **117**. The spindle **256** can have a length ranging from five to 30 millimeters. An end cap or nut **266** substantially similar to end nut **118** but shorter in length can be further provided (see FIGS. **49-51**). The end nut can have a length ranging from three to 30 millimeters. The proximal portion **142** of spindle **256** is shown as being captured or seated in socket **172** in the distal portion **162** of end nut **266** in FIG. **52** so that the spindle and end cap are coaxially aligned in their operational positions relative to each other.

The components of actuation assembly **241** can be loaded into head **239** of dual fixation screw rod **232**, and operated therein with respect to first and second proximal fixation screws **233** and **234**, in substantially the same manner as discussed above with respect to apparatus **61**. Sleeve **242** is shown in FIG. **40** in its distal position. The inclusion in apparatus **241** of the second fixation screw **234** minimizes the need for a set screw, such as set screw **119**, and preferably eliminates the need for such a set screw. In this regard, the second proximal fixation screw is included in the means or mechanism of the rod **232** for preventing rotation of the head of the femur relative to the first proximal fixation screw **233** during use of rod **232**. It is appreciated that other means, such as a nail, peg, blade or bolt, can be included in an intramedullary rod of the present invention for inhibiting rotation of the head of the femur relative to the first fixation screw. The optional second aperture **237** and second proximal fixation screw **234** allow sliding compression so as to prevent rotation and to adapt the apparatus or device to a variety of applications.

A further embodiment of the intramedullary rod with pivotable fasteners of the present invention is illustrated in FIG. **53** wherein an apparatus **271** substantially similar to apparatus **61** and **231** is provided. Like reference numerals have been used to describe like components of apparatus **61**, **231** and **271**. Intramedullary rod or nail **272** of the apparatus **271** is substantially similar to rods **62** and **232** and has any suitable first and second proximal fasteners, shown, as first and second proximal fixation screws **233** and **234**. The first screw **233** is pivotably received within first transverse aperture **236** extending along axis **92**. The second screw **234** is pivotably received within a second transverse aperture **273** extending along an axis **274**. The aperture **273** can be substantially identical to transverse aperture **236** except that axis **274** of the second transverse aperture **273** is not parallel to the axis **92** of the first transverse aperture **236**. The first and second fasteners **233** and **234** extend nonparallel to each other, may or may not be of the same length and may or may not he of the same type of fastener. The apertures **236** and **273** are provided in a head **276** of the rod **272** that is substantially similar to head **239** of rod **232**. An actuation mechanism or assembly (not shown) substantially similar to actuation mechanism **241** but modified to provide for the nonparallel disposition of apertures **236** and **273** is provided.

Another embodiment in the form or apparatus **281** is illustrated in FIG. **54** and can include an intramedullary rod **282** substantially similar to rods **62** and **2.32**. Like reference numerals have been utilized to describe like components of rods **62**, **232** and **282**. The intramedullary rod **282** has any suitable first, second and third proximal fasteners, shown as first, second and third proximal fixation screws **233**, **234** and **283**, pivotably received within respective first, second and third transverse apertures **236**, **237** and **286**. The third proximal fixation screw **283** can be identical to one or both of first and second proximal fixation screws **233** and **234**, and the third transverse aperture **286** can be identical to one or both of first and second transverse apertures **236** and **237**. The first, second and third fasteners **233**, **234** and **283** may or may not extend parallel to each other, may or may not be of the same length and may or may not be of the same type of fastener. In the illustrated embodiment, the fasteners **233**, **234** and **283** extend parallel to each other. The apertures **236**, **237** and **286** are provided in a head **287** of the rod **282** that is substantially similar to head **239** of rod **232**. An actuation mechanism or assembly (not shown) substantially similar to actuation mechanism **241** but modified to provide for the third transverse aperture **286** can be provided.

Yet a further embodiment of the intramedullary rod with pivotable fasteners of the present invention is illustrated in FIGS. **55-56** wherein an apparatus **296** substantially similar to apparatus **61** and **231** is provided. Like reference numerals have been used to describe like components of apparatus **61**, **231** and **296**. Intramedullary rod or nail **297** of the apparatus **296** is substantially similar to rods **62** and **232** and has any suitable first and second proximal fasteners, shown as first and second proximal fixation screws **233** and **234**. The first screw **233** is pivotably received within first transverse aperture **236** extending along axis **92**. The second screw **234** is pivotably received within a second transverse aperture **298** extending along an axis **299**. The second transverse aperture **298** can be substantially identical to the first transverse aperture **236** except that axis **299** of the second transverse aperture **298** is not parallel to the axis **92** of the first transverse aperture **236**. More specifically, axis **299** is circumferentially angled about the longitudinal axis **66** of rod **297** relative to axis **92**, as shown in FIG. **56** by angle θ. Angle θ can be any suitable number. Axes **92** and **299** can extend at the same angle relative to longitudinal axis **66**, such as axes **92** of rod **232** as shown in FIG. **38**, or can extend at different angles relative to longitudinal axis **66**, such as axes **92** and **274** of rod **272** as shown in FIG. **53**. The first and second fasteners **233** and **234** may or may not he of the same length and may or may not be of the same type of fastener. The apertures **236** and **298** are provided in a head **301** of the rod **297** that is substantially similar to head **239** of rod **232**. An actuation mechanism or assembly (not shown) substantially similar to actuation mechanism **241** but modified to provide for the different circumferential alignment of apertures **236** and **298** is provided.

It can be seen from the foregoing various embodiments of the intramedullary rod with pivotable fasteners of the present invention that such fasteners can be of any suitable number. Where multiple fasteners are provided, the fasteners can extend parallel to each other or at various angles to each other relative to the longitudinal axis and about the longitudinal axis of the nail. Extrapolations of the illustrated apparatus can be provided, for example where three nonparallel fasteners are provided, where multiple fasteners are circumferentially aligned relative to each other about the longitudinal axis of the rod but spaced the same distance from the proximal end of the rod or where two or more first fasteners are circumferentially aligned relative to such longitudinal axis and one or more second fasteners are circumferentially spaced apart about such longitudinal axis relative to the first fasteners.

Although the apparatus of the invention has been illustrated as having a separate transverse aperture in the rod for each fastener, it is appreciated that multiple fasteners can pivotably extend through a single transverse aperture. In one such embodiment in which a single transverse aperture receives two fasteners, one or both of the aperture in the rod and the aperture in the actuation mechanism has a configuration that narrows between two end portions of such aperture such that the two fasteners extending through respective end portions of such aperture are separated from each other by the narrowed material of the rod and/or the actuation mechanism.

Several procedures for utilizing the intramedullary rod with pivotable fixation screws of the present invention are illustrated in FIGS. **57-59**, where apparatus **231** with dual fixation screw rod **232** is shown in use to repair peritrochanteric fractures of a femur **311**. More specifically, **232** rod is shown repairing a femoral neck fracture **316**, an intertrochanteric fracture **317** and a subtrochanteric fracture **318**, respectively, in FIGS. **57-59**. Previous to the procedure of the invention, the rod **233** was introduced through the greater trochanter **321** into the medullary canal **322** in the shaft **323** of the femur. Suitable holes **324** were made in the side of the greater trochanter to allow insertion of the first and second fixation screws **233** and **234** into the lateral transverse openings **93** of the respective first and second transverse apertures **236** and **237** in the head **239** of the rod. The fixation screws were thereafter screwed into the head **326** of the femur **311**. In each instance, however, further adjustment of the head of the femur may be required either because the fracture is malreduced, the entry point for the rod in the greater trochanter was too lateral or a combination of the foregoing. In one procedure of the invention, a suitable drive (not shown) element is introduced through the entry point **327** in the femur into the proximal opening **103** in the head **239** of the nail **232** and through the end nut **266** so as to seat within the drive socket **153** in the neck portion **142** of the spindle **256**. The spindle **256** is rotated by the drive element, for example in a clockwise direction, so that the external threads **141** on the spindle engaged with the internal threads **131** on the proximal portion **122** of the insert or sleeve **242** and cause the insert **242** to slide or move proximally within the head **239** and thus cause each of the first and second proximal fixation screws **233** and **234** to pivot upwardly toward the head **239** of the rod, that is in a clockwise direction in FIGS. **57-59**, until the fracture is reduced and the head **326** of the femur **311** is brought out of varus and thus properly positioned relative to the remainder of the femur, as shown in phantom lines in FIGS. **57-59**. The first and second proximal fixation screws are identified as **233'** and **234'** in FIGS. **57-59** when in their second position in which they have been pivoted upwardly toward the head **239** of the rod **232**.

The capture of the neck portion **142** of the spindle **256** in the socket **172** of the end nut **266** inhibits movement of the spindle **256** from its coaxial position with the longitudinal axis of the head **239** and thus inhibits undesirable movement of the insert **242**, and the first and second fixation screws **233** and **234** retained in position by the insert, that may result from such misalignment of the spindle **256** in the head **239** of the rod. The second fixation screw **234** inhibits, if not prevents, rotation of the femoral head **326** relative to the first fixation screw **233**.

It is appreciated that the apparatus of the invention can include more than two proximal fasteners to fixate head **326** of the femur, or a portion of any other suitable bone, and be within the scope of the present invention.

Other embodiments of the intramedullary rod of the present invention, for example with one or more pivotable fasteners and one or more fixed fasteners carried by the proximal portion of the rod, can be provided. Apparatus **331**, illustrated in FIGS. **60-64**, includes an intramedullary rod **332** substantially similar to rod **62** and like reference numerals have been utilized to describe like components of rods **62** and **332**. The intramedullary rod **332** has first and second proximal fasteners **63** and **333** that can be of any suitable type, including a fixation screw, a screw, a peg, a helical blade or any other fixation device. The fasteners **63** and **333** can be solid, as shown in FIG. **62** with respect to second fastener **333**, or fenestrated, as shown in FIG. **62** with respect to first fastener **63**. The first and second fasteners **63** and **333** may or may not be of the same length and may or may not be of the same type of fastener. For example, the first fastener **63** may be a screw and the second fastener **333** may be a peg or blade. For simplicity, the proximal fasteners are referred to herein and illustrated as first and second proximal fixation screws **63** and **333**.

Second screw **333** is formed from an elongate body **336** having a length ranging from 30 to 200 millimeters and a diameter ranging from two to 20 millimeters. The elongate body **336** can he formed from any suitable material such as stainless steel and includes a proximal portion **337** having a drive head **338** and a distal portion **339** that may be provided with external threads **341** extending to a sharpened distal end or tip **342**. In the embodiment of the second screw **333** illustrated in FIG. **62**, external threads are provided along the entire length of the elongate body **336**. It is appreciated that a screw **333** having external threads **341** at other locations, for example at both the proximal portion **337** and the distal portion **339** but not in the central portion, or at solely the proximal portion **337**, can be provided.

First proximal fixation screw **63** is pivotably received within first aperture **91** and extends along first axis **92**. Second proximal fixation screw **333** is nonpivotably received within a second aperture **346** and extends along a second axis **347**. The apertures **91** and **346** are provided in a head **348**, substantially similar to head **67**, of the rod **332**. In one embodiment, an actuation mechanism or assembly **351**, substantially similar to actuation mechanism **101**, can be provided within the head **348** for pivoting the first proximal fixation screw **63**. Actuation mechanism **351**, shown assembled in FIG. **62**, can include an insert or sleeve **352** substantially similar to the insert **116** of mechanism **101**.

Second aperture **346** can optionally be internally threaded, as illustrated in FIG. **62**. In embodiments where both the proximal portion **337** of the second proximal fixation screw **333** and the second aperture **346** are threaded, and thus threadedly engage each other, an actuation mechanism **101** need not be provided for pivoting the first proximal or dynamic fixation screw **63** as the second screw **333** can be utilized for the pivoting of the first screw **63**.

Second fixation screw **333** and thus second aperture **341** can be proximal or distal or first aperture **91** and is shown as being distal of the first aperture **91**. It is appreciated that a second or fixed fixation screw can be provided both proximally and distally of the one or more pivotable fixation screws of the present invention, between the pivotable fixation screws or any combination of the foregoing. In one embodiment, the second aperture **341** is located distally of the first aperture a distance ranging from two to 30 millimeters side to side and in another embodiment a distance of approximately seven millimeters side to side. Sleeve **352** is provided with a notch or cutout **353** at bottom end **129** for receiving the portion of elongate body **336** extending through head **348** and in the path of the sleeve **352** when the sleeve is moved distally within the head (see FIGS. **63-64**). In one embodiment, the first and second proximal fixation screws **63** and **333** extend in the same plane, as can be seen in FIG. **61**, although it is appreciated that the fixed screw **333** need not be in the pivot plane of the pivotable screw **63**. When the screws **63** and **333** are disposed in the same plane, the center of cutout **353** is circumferentially aligned with the center of transverse opening **124** as shown in FIG. **64**.

The second proximal fixation screw **333** can be disposed at any suitable angle β relative to longitudinal axis **66** of the elongate body **64**. For example, the screw **333** can be inclined proximally, as shown in FIGS. **60-62**, be inclined distally (not shown) or be orthogonal to the axis **66**. In one embodiment, the screw **333** is inclined relative to axis **66** at an angle β ranging from 90° to 170° and in another embodiment at an angle β ranging from 120° to 140° (see FIG. **62**). In one embodiment, the distal portion **339** of the second fixation screw **333** is inclined relative to the pivotable fixation screw **63** so as to contact or abut the first fixation screw **63**, and preferably contact or abut the first fixation screw **63** between the proximal portion **202** and distal portion **206** of the screw **63** (see FIG. **62**).

Apparatus **31** can be used in any suitable procedure for repairing a bone of a mammalian body, for example a femur in a leg. In one procedure utilizing apparatus **31**, for example in one of the procedures illustrated in FIGS. **57-59** and discussed above, rod **332** is introduced through the greater trochanter **321** into the medullary canal **332** in the shaft **323** of the femur **311**. Suitable holes **324** are made in the side of the greater trochanter to allow insertion of the first and second fixation screws **63** and **333** into respective first and second apertures **91** and **346** of the rod **332**. First screw **63** can be initially introduced through rod **332** and screwed into the head **326** of the femur **311**. If necessary, the first screw **63** is pivoted relative to longitudinal axis **66** of rod **332** in the manner discussed above. Thereafter, the second screw **333** is introduced through rod **332** and screwed into the femur head **326**. The nonpivotable or fixed second screw can extend parallel or at an inclination to the first screw **63** and in either case serves to enhance the mechanical strength of apparatus by sharing the torque and other forces being experienced by the first screw **63** and the actuation assembly **351** supporting the first screw **63**.

The nonpivotable or fixed screw **333** can be sized and introduced a sufficient distance so as to engage the side of the first screw, for example at a distance proximal of the distal tip **208** of the first screw **63**. When the second or fixed screw **333** is so disposed relative to the first screw **63**, the fixed screw serves to buttress or statically support the inferior or bottom of the first screw and thus minimize undesirable pivoting of the first screw relative to the rod **332** after final placement of the apparatus **331** within the femur **311**. The buttressing and support of the first or dynamic screw **63** by the second or static screw **333** can be enhanced when the proximal portion **337** of the screw **333** and the second aperture **346** threadedly engage each other so that the second screw is nonslidably engaged with the head **348**.

In a further aspect of the invention, and after the fixed screw **333** is abutting the side of the first screw **63**, the fixed screw **333** can be further advanced relative to the head **348** of the rod **332** so as to cause the first screw **63** to pivot relative to the head **348**, for example to pivot the first screw **63** toward proximal opening **77** of the rod **332**. Such pivoting of the first screw **63** may be desirable when fine adjustments to the first screw **63** are desired, and can be accomplished when the proximal portion **337** of the screw **333** and the second aperture **346** are not threaded, in which case screw **333** is advanced by its threaded engagement with the head **326** of the femur **311**, or when the proximal portion **337** and the second aperture **346** are both threaded, in which case the screw **333** is advanced solely or additionally by its threaded engagement with the head **348** or the rod **332**. The length of the static screw **333** can be selected to choose the amount by which the dynamic screw **63** is pivoted relative to head **348**. In this regard, in the illustrated embodiment the greater the length of the static screw **333** the greater the amount by which the dynamic screw **63** is pivoted relative to head **348**.

It is appreciated that an actuation mechanism **351** need not be provided when the fixed screw **333** is used solely as the means for pivoting the dynamic screw **63**. In one such embodiment, the dynamic screw pivots freely relative to head **348** and is supported in its desired position by static screw **333**, either solely or in combination with another suitable securement mechanism (not shown). It is also appreciated that other means can be provided for pivoting the dynamic screw **63** and be within the scope of the present invention.

In another aspect of the invention, a locking mechanism is provided for use with an implantable medical device. The locking mechanism can be utilized with any medical device having a rotatable, control, moveable or other element on the outside or inside thereof. In one embodiment, the locking mechanism can be used with a threaded element, for example an internal or external threaded element of a medical device. In one embodiment the element can be an element for controlling another moveable element of a medical device, for example a control element coupled to a longitudinally moveable or slidable element of the medical device. In one embodiment described and illustrated herein, the medical device is an implantable intramedullary rod.

One embodiment of an implantable medical device having a locking mechanism of the type discussed above is apparatus **401** illustrated in FIGS. **65-81**. Apparatus **41** is similar to apparatus **61** and includes an intramedullary rod or nail **402** substantially similar to nail **62**. Like reference numbers have been used to describe liked components of nails **402** and **62**. Although the rod **402** can be used in any bone of a mammalian body, in one embodiment rod **402** is for use in a femur and may thus be called a femoral nail **402**. Nail **402** includes an elongate body **403**, which can be similar to elongate body **64** of nail **62** that extends along a longitudinal or central axis **404** and can have a proximal portion or head **406**, a central portion or neck **407** and a distal portion or shaft **408** that terminates at a distal tip **71**. The nail **402** is illustrated schematically in the figures, where head **406**, neck **407** and shaft **408** are not necessary drawn to scale. Like elongate body **64**, body **403** may curve in at least one portion of shaft or stem **408** to align the rod **402** along the length of the marrow canal of the femur or other bone in which the rod is to be inserted. Elongate body **403**, including tubular head or head **406**, neck **407** and shaft **408**, can have a size, shape and construction similar to body **64**, for example as such parts of body **64** are discussed above. In this regard, for example, elongate body **403** can be provided with a longitudinally-extending passageway or bore **76** of the type discussed above for permitting the rod to slide along a guide wire (not shown) during insertion of the rod into the femur or other bone of the mammalian body. Furthermore at least one bore **81** can be provided in the distal end portion of stem **408** adjacent tapered tip **71** for receiving at least one distal fastener of the type discussed above and including screw **82**.

Head **406** of rod **402** may include an actuation or adjustment mechanism or assembly **411**, which can be similar to adjustment mechanism or assembly **101** described above, for selectively pivoting proximal fixation screw **63** from a first angled position relative to the nail head **406** to a second angled position relative to the nail head. In this regard and as illustrated in FIGS. **78** and **68**, the proximal portion central passageway **76** of the nail **402** can be hallowed to form a longitudinally-extending proximal recess **412**, which can be substantially similar to recess **102** discussed above, that communications with proximal opening **103** in the proximal end of the head **406**. As illustrated in FIG. **68**, proximal recess **412** can have a proximal or threaded portion **412***a* adjacent proximal opening **103**, a circular central portion **412***b* and a distal portion **412***c* that in one embodiment, discussed and illustrated herein, is noncircular in cross section and sometimes referred to herein as the segmented circular portion or segmented portion **412***c*. Tubular head **406** is formed by an outer wall **413**, which is substantially annular in shape and formed by the proximal recess **412**, having a first side portion **413***a* and an opposite second side portion **413***b* relative to central longitudinal axis **404**.

Head **406** is provided with at least one aperture **416** extending along a transverse axis **417** inclined at an angle to longitudinal axis **404**. Head **406** is adapted to receive fastener or screw **63** in aperture **416**, which is distinct from proximal recess **412** of elongate passageway **76**, but formed in part by the proximal recess **412**. In one embodiment, head **406** is provided with a single aperture **416**. More specially, the aperture **416** is formed by first and second spaced apart openings extending respectfully through the outer, opposite side portions of wall **413** of the head **406**. In this regard, a first or lateral transverse opening **421** is provided on one side of wall **413** or first side portion **413***a* of the wall and a second or medial transverse opening **422** is provided on the other side of the wall **413** or second side portion **413***b* of the wall. At least one of the openings **421** and **422** can be elongate or oblong in a direction parallel to longitudinally axis **404** so as to facilitate pivoting of the fixation screw **63** relative to head **406** about an axis (not shown) extending orthogonally to longitudinally axis **404** and aperture axis **417**. In one embodiment, as illustrated in FIGS. **65**, **67** and **68**, the lateral transverse opening **421** is so elongate or oblong. Axis **417** is centered on aperture **416** and can extend relative to longitudinal axis **404** at an angle and in one embodiment at an angle of approximately 140 degrees measured from the portion of head **406** distal of head aperture **416**.

Aperture **416** is formed by an inner circular surface **423** centered on axis **417**. A cutout **424** formed by a cutout semicircular surface **426** is provided in the portion of outer wall **413** that opens onto and forms the proximal portion of lateral transverse opening **421**. Cutout surface **426** is centered on an axis (not shown) within the angular range of axis **417** relative to longitudinal axis **404** disclosed above and in one embodiment on an axis extending at an angle of approximately 120 degrees measured from the portion of head **406** distal of aperture **416**. In one embodiment, the diameter of inner circular surface **423** and cutout surface **426** are each approximately equal to the diameter of fixation screw **63** such that when the fixation screw is extending at an angle of approximately 140 degrees relative to the head **406** and axis **404** the cylindrical body **201** of the screw **63** is seated flush with the inner circular surface **423** (see FIG. **81**), and when the fixation screw is extending in an angle of approximately 120 degrees relative to the head **406** and axis **404** the cylindrical body **201** of the screw **63** is seated flush with the cutout semicircular surface **426** (see FIG. **68**). The distal portion of medial transverse opening **422** in wall second side portion **413***b* is provided with a convex variable radius or rounded contact surface **428** at the radial outside of outer wall **413**.

Although the actuation or adjustment mechanism **411** for pivoting the proximal fixation screw **63** can be of any suitable type, in one embodiment mechanism **411** includes an insert, element or sleeve **436**, a threaded element or control element **437**, an alignment or set screw **438** and a locking mechanism **439**, illustrated as assembled in FIG. **68** and separately in FIGS. **69-79**. Unless otherwise indicated, each of these components can be made any suitable material such as stainless steel.

Sleeve **436**, which in one embodiment is one example of the broad categories of elongate elements or movable elements, can be formed from elongate tubular element or member **441** having a proximal portion or end portion **441***a* and a distal portion or end portion **441***b* and extending along a longitudinal or central axis **442**. Elongate member **441** is formed with a bottom surface **443** which is semicircular in cross section and extends the entire length of the elongate member. Proximal portion **441***a* includes a circular annulus or ring **446** and a lip **447** spaced proximally from annulus **446** by an annular or recess **448**. Annulus forms the periphery of the proximal portion **441***a*, and of the elongate member **441**, and is substantially circular in shape. Lip **447** extends around the periphery of the proximal portion **441***a*, but is provided with an opening or cutout **449** at, the top thereof such that the lip **447** does not extend around the top of elongate member **441**. Elongate member **441** is provided with an elongate cutout **451** extending distally of annulus **446**, and the cutout **451** is formed by a flat **452** which is planar and parallel to central axis **442**. A concave arcuate surface **453** extends from each side of the flat **452** to bottom surface **443**. As such, distal portion **441***b* of the sleeve **436** is noncircular in cross section and in one embodiment its segmented circular cross section, as described above, corresponds generally with the cross section of segmented portion **412***c* of the head proximal recess **412**. Distal portion **441***b* of the elongate member **441** is sized and shaped to slidably move longitudinally within segmented circular portion **412***c* of the proximal recess **412** of the head **406**. Annulus **446** of the sleeve of **436** is externally sized and shaped to slidably move longitudinally move within central portion **412***b* of the head proximal recess **412**. A passageway or bore **456** extends the length of elongate member **441** from a proximal opening in annulus **446** to a distal opening at the distal end of the member **441**. In one embodiment, bore **456** is internally threaded at its proximal portion **456***a* and has an internal diameter less than the inner diameter of lip **447**.

Sleeve **436** is provided with at least one aperture **461** extending along an axis **462** inclined at an angle to central axis **442** and adapted to receive fastener or fixation screw **63**. Aperture **461** is distinct from bore **456**, and the bore **456** extends through the aperture **461**. In one embodiment, sleeve **436** is provided with a single aperture **461**, which opens onto bottom surface **443** at a first or lateral transverse opening **463** and opens onto flat **452** and arcuate surface **453** at a second or medial transverse opening **464** At least one of the openings **463** and **464** can be elongate or oblong in a direction parallel to central axis **442** so as to facilitate pivoting of the fixation screw **63** relative to head **406** and sleeve **436** about an axis (not shown) extending orthogonally to sleeve central axis **442** and aperture axis **462**. In one embodiment, medial transverse opening **464** is so provided with a cutout at its distal portion so as to be elongate or oblong. Axis **462** can be centered on aperture **461** and can extend relative to central axis **442** at an angle and in one embodiment at the same angle that axis **417** extends relative to longitudinal axis **404**. The aperture **461** can be formed by an inner circular surface **406**, shown most clearly in FIG. **71**, which is centered on aperture axis **462**. Aperture **461** can further include a cutout **467** along its distal end adjacent medial transverse opening **464** that is formed by a semicircular cutout surface **468** which can be centered on an axis (not shown) within the angular range of aperture axis **462** relative to central axis **442** and in one embodiment on an axis extending at an angle of approximately 120 degrees measured from the portion of sleeve **436** distal of sleeve aperture **461**. The proximal portion of lateral transverse opening **463** is provided with a convex variable radius or rounded contact surface **471**. The internally-threaded proximal portion **456***a* of sleeve bore **456** can extend distally to transverse aperture **461**.

Rotatable control element **437**, which in one embodiment is one example of the broad categories of elements which

include control elements, movable elements and threaded elements, is carried by head **406** and accessible at proximal opening **103** for causing the adjustment mechanism **411** to pivot fixation screw **63** relative to the head **406**. The control element can be of any suitable type and in one embodiment includes a spindle, screw or worm gear **437** formed from a cylindrical body **476** (see FIGS. **68**, **80** and **81**) extending along a central or longitudinal axis (not shown). Cylindrical body **476** includes a first or proximal portion **476***a* that can have an externally threaded outer surface diametrically sized for threaded engagement with threaded portion **412***a* of proximal recess **412** of the head **406**. Second or distal portion **476***b* of the cylindrical body **476** can include an annular flange **477** spaced from externally-threaded proximal portion **476***a* by an annular recess **478**. The annular flange **477** is diametrically sized and shaped to snugly seat within recess **448** of the sleeve **436**. Similarly, annular recess **478** of the cylindrical body **476** is diametrically sized and shaped to snugly receive lip **447** of the sleeve **436**. Annular flange **477** can be so coupled to sleeve **436** by sliding the flange **477** transversely relative to sleeve **436** though cutout **449** into the recess **448**. When worm gear **437** is coupled or connected to sleeve **436** in this manner, the central axis of the worm gear is coincident with central axis **442** of the sleeve **436** and the worm gear is longitudinally fixed or locked relative to the sleeve **436**. Annular flange **477** and annular recess **478** are configured and sized, however, to permit worm gear **437** to rotate relative to sleeve **436** when such elements are so coupled together.

Worm gear **437** controls the longitudinal position and movement of sleeve **436** when such elements are disposed within head **406**. In this regard, cylindrical body **476** can be tubular in conformation and be provided with a central passageway or drive socket **479** extending longitudinally through the body **476**. Socket **476** has a noncircular cross section of any suitable type or shape and in one embodiment the cross section is hexagonal in shape. When sleeve **436** and worm gear **437** are so disposed within nail head **406**, a suitable drive element seated within drive socket **479** of the worm gear **437** can serve to screw or rotate the worm gear **437** proximally or distally within the internally-threaded portion **412***a* of head proximal recess **412**. Such advancement or withdrawal of the worm gear **437** within head **406** simultaneously causes sleeve **436** to advance or withdraw, in a one-to-one manner with the longitudinal movement of the worm gear **437**, in central portion **412***b* and segmented portion **412***c* of the head proximal recess **412**. In one embodiment, for example, worm gear **437** can be rotated in a clockwise direction from proximal opening **103** so as to cause sleeve **436** to move distally within the head **406**, and rotated in a counter-clockwise direction from proximal opening **103** so as to cause the sleeve **436** to move proximally within the head **406**. In one embodiment, the diameter of drive socket **479** is larger than the diameter of the internally-threaded proximal portion of longitudinal bore **456** of the sleeve **439** and is preferably coaxially aligned with sleeve bore **456**.

Locking mechanism, assembly or device **439** is coupled to worm gear **437** and configured to preclude rotation of the worm gear relative to head **406** when the locking mechanism is in a first position and permit rotation of the worm gear **437** relative to the head **406** when the locking mechanism is in a second position. Although it is appreciated that locking mechanism **439** can have any suitable configuration and construction for rotatably locking and unlocking worm gear **437** within head **406**, in one embodiment the locking mechanism includes a first locking element **486** and a second locking element **487** centered on a central or longitudinal axis **488** of the locking mechanism **439**. The second locking element **487** is moveable longitudinally between a first position in which the second locking element **487** engages the first locking element **486** so as to be rotatably locked with the first locking element and a second position in which the second locking element **487** is disengaged from the first locking element **486** so as to be rotatable relative to the first locking element.

In one embodiment, the first locking element is annular in shape and can be an annular element. In one embodiment the first element **486** can be in the form of a nut that can be externally treaded and diametrically sized so as to threadably engage threaded portion **412***a* of proximal recess **412** in head **406**. Annular nut **486** can include a circular inner surface **491** centered on central axis **488** for forming a bore **493** extending along the axis **488** through a portion of the nut **486**. A flange **496** extends radially inwardly from the distal end of inner circular surface **491** and terminates at annular or circular surface which is coaxial with inner circular surface **491**. Nut **486** has a distal surface **498** which includes flange **496** and in one embodiment the surface **498** is planar and orthogonal to central axis **488**. A plurality of locking or engagement means or elements are provided on distal surface **498** and can be of any suitable type, including a plurality of recesses, protuberances or a combination of recesses and protuberances. In one embodiment, such locking means includes a plurality of first upstanding protuberances or dogs **501** extending longitudinally outwardly from the distal surface **498**. In one embodiment, a plurality of first dogs **501** are spaced circumferentially around surface **498** and in one embodiment the first dogs **501** are circumferentially spaced equally apart around the distal surface **498**. A suitable means is included within nut **486** for rotating the nut within threaded portion **412***a* of head proximal recess **412** and can include spaced-apart first and second bores **502** extending longitudinally inwardly from the proximal end of the nut. In one embodiment, bores **502** are diametrically opposed on opposite sides of bore **493** and are sized to receive a suitable drive tool for so rotating the nut **486** with nail head **406**.

In one embodiment, the second drive element **487** is annular in shape and can be an annular element. In one embodiment, the second drive element can be in the form of a washer having opposite first and second planar surfaces **506**, **507** extending parallel to each other and a bore **508** extending between the surfaces **506** and **507**. The washer **487** has an outer diameter smaller than the inner diameter of threaded portion **412***a* of the head proximal recess **412**. Similar to distal surface **498** of nut **486**, first surface **506** of the washer is provided with a plurality of locking or engagement means or elements of any suitable type, including a plurality of recesses, protuberances or a combination of recesses and protuberances. In one embodiment, such locking means include a plurality of second upstanding protuberances or dogs **509** extending longitudinally outwardly from the first surface **506**. In one embodiment, the plurality of second protuberances **509** are spaced circumferentially around the first surface **506** and in one embodiment the second dogs circumferentially spaced apart so as to register with or engage first dogs **501** and thus preclude relative to rotation between washer **47** and nut **46** when the washer **487** and second dogs **509** are in the first position. In this manner, second dogs **509** cooperatively engage first dogs **501** when washer **487** is in the first position.

Locking mechanism **439** can further include a driver element or driver **511** having a proximal portion **511***a* with a circular outer surface and a distal portion or drive head **511***b* with an outer surface that is non-circular in cross section. The diameter or at least the distal portion of the circular outer surface approximates the diameter of the inner circular surface of nut flange **496**. The cross-sectional shape of distal end or drive head **511***b* can be, for example, triangular, square, hexagonal or octagonal, and preferably corresponds in size and configuration and cooperates with drive socket **479** of the worm gear **437**. A flange **512** extends radially outwardly from proximal portion **511***a* at the proximal end of driver **511**. Flange **512** has an outer circular surface with a diameter that approximates the diameter of the inner circular surface **491** of nut **486**. A drive socket **513** extends longitudinally inwardly from the proximal end of driver **511** and preferably has a cross section which is non-circular in shape, for example similar to the cross-sectional shape of drive head **511***b* discussed above, so that when the socket **513** is engaged by a suitable tool it can serve to cause rotation of the driver **511**. A longitudinally-extending bore **514** extends distally from drive socket **513** through the remainder of the driver **511**.

For assembly, driver **511** extends through nut **486** and washer **487**. More specially, the driver **511** extends through bore **493** and flange **496** of the nut **486** until the nut flange **496** is in close proximity to driver proximal portion **511***a* and driver flange **512** is seated within bore **493** and in one embodiment flush with the proximal end of nut **486**. In one embodiment, flange **496** of the nut engages the outer circular periphery of proximal portion **511***a* of the driver **511**. Washer **487** extends around distal portion or end of driver proximal portion **511***a* distal of nut **46** so that when locking mechanism **439** is in its first or rest position second dogs **509** of washer **487** are cooperatively engaged and locked with first dogs **501** of nut **486**. The washer **487** is secured to proximal portion **511***a* of the driver by any suitable means such as welding. Nut **486** is not secured to driver **511** and thus longitudinally moveable relative to the driver.

Means is included with locking mechanism **439** for urging washer **487** towards its first or locking position relative to nut **486** in which first and second dogs **501**, **509** are cooperatively engaged and thus rotatably locked relative to each other. in this regard, an annular recess **516** is provided between nut **46** and driver **511**. Recess **516** is formed at its outer periphery by inner circular surface **491** of nut **486**, at its inner periphery by the outer circular surface of driver proximal portion **511***a*, at its proximal extremity by flange **512** of driver **511** and its distal extremity by flange **496** of nut **486**. A suitable spring, for example an annular wave spring **517**, is disposed in recessed **516** and extends around driver **511**. The spring **571** has a proximal end portion **517***a* engaging flange **512** of driver **511** and a distal end portion **517***b* engaging flange **496** of the nut **486**.

Locking mechanism **439** is movable between a first position in which driver **511** can rotate freely relative to nut **486** and a second position in which the driver **511** is rotatably locked with the nut **486**. Spring **517** urges locking mechanism **439** towards its first or rest position, illustrated in FIGS. **76** and **82**, in which the springs **517** urges flange **512** of the driver **511** longitudinally away from flange **496** of nut **486** so that second dogs **509** on first surface **506** of washer **487** register and rotatably lock with first dogs **501** on distal surface **498** of the nut **46**. When driver **511** is urged longitudinally in a distal direction, for example by insertion of a suitable drive tool in drive socket **513** of the driver **511** and exertion of a longitudinal force in the distal direction on the tool and thus the driver **511**, washer **487** that is rigidly secured proximal portion driver **511***a* of the driver is moved longitudinally against the force of spring **517** away from distal surface **498** of nut **486** so that the second dogs **509** of the washer **487** separate and disengage from first dogs **501** of the nut **46** to a second or disengaged position, illustrated in FIG. **83**, in which the combined driver **511** and washer **487** unit can be rotated relative to nut **486**. As such, washer **487** is spaced longitudinally from nut **486** when the washer is in its second position.

Set screw **438** can be of any suitable type and similar to set screw **119** discussed above. In one embodiment, set screw **438** is cylindrical in conformation and externally threaded. The set screw **438** can include a rounded distal end **522** and a suitable drive socket **523** provided at its proximal end. Such set screw is diametrically sized so as to be capable of being passed longitudinally through drive socket **513** and bore **514** of drive **511** and into bore **456** of the sleeve **436** to threadably engage the threaded proximal portion **45*ba*** of the sleeve bore **456**.

The internal components of head **406** can be loaded in proximal recess **412** of the head in any suitable manner. In one such method of assembly, sleeve **436** is introduced through threaded portion of **412*a*** so that distal portion **441*b*** of the sleeve is seated within segmented portion **412*c*** of the recess **412** and annulus **446** of the sleeve is seated within central portion **412*b*** of the recess **412**. As discussed above, distal portion **441*b*** has an external cross section similar to the internal cross section of segmented portion **412*c*** so that sleeve **436** is rotatable locked but longitudinally movable or slidable in nail **402** relative to axis **404** of the nail. Aperture **461** of sleeve **436** is generally registered with aperture **416** of head **406** in the operational longitudinally positions of sleeve **436** within the nail head **406**.

Worm gear **437** is coupled to proximal portion of sleeve **436**, in the manner discussed above, prior to the full insertion of the sleeve elongate member **441** within head recess **412**. The externally-threaded proximal portion **476*a*** of the worm gear **437** threadably engages threaded portion **412*a*** of the nail head **406** during longitudinal insertion of sleeve **436** and worm gear **437** through proximal opening **403** of the head **406**. Drive head **511*b*** of locking mechanism **439** can be inserted into drive socket of **479** of worm gear **437**, so as to couple the locking mechanism **439** to the worm gear **437**, before the worm gear **437** is entirely threaded into head recess **412** and properly positioned longitudinally relative to the worm gear **437** before being threaded into threaded portion **412*a*** of the proximal recess **412**. When locking mechanism **439** is in its first position, a suitable drive tool can be inserted into drive socket **523** so as to rotate both the locking mechanism **439** and worm gear **437** during the introduction of the components of adjustment mechanism **411** into the head.

Once sleeve **436**, worm gear **437** and locking mechanism **439** have been properly positioned longitudinally within proximal recess **412**, and longitudinally positioned relative to each other, nut **486** of the locking mechanism is secured to the head **406** and in one embodiment locked or secured against both rotatable and longitudinally movement within the head **406**. In one embodiment, the engaged invisible internal threads of threaded portion **412*a*** of the head **406** and external threads at the proximal end of nut **486** are punched at one or more positions, for example at a plurality of circumferentially-spaced apart positions, by a suitable punching tool so as to preclude nut **46** from being rotatably moved in a proximal direction, and thus withdrawn, from threaded portion **412*a*** of recess **412**.

Nail **402** can be placed within a bone in any suitable manner and for example as discussed above and as discussed below. in one method of inserting the nail **402** into a bone of a mammalian body, a guide wire is first introduced into the bone and the nail is then threaded over the proximal end of the guide wire for proper placement and positioning in the bone. In this regard, the proximal end of the guide wire can be inserted through passageway **76** of the elongate body **403**, though adjustment mechanism **411** by means of bore **456** of sleeve **436** and drive socket **479** of worm gear **437**, and through locking mechanism **439** by means of bore **514** and drive socket **513** of driver **511**. After the nail **402** has been properly positioned within the bone, the guide wire is removed from the nail **402** through proximal opening **103**.

A suitable fastener such fixation screw **63** can be introduced through head **406** by means of lateral transverse opening **421**, aperture **461** of sleeve **436** and medial transverse opening **422** and properly positioned within the bone. In this regard, lateral transverse opening **421** in first side portion **413*a*** of wall **413** receives the proximal portion or head **67** of the fastener and medial transverse opening **422** in second side portion **413*b*** of wall **413** receives the distal portion or shaft **69** of the fastener **63**. Similar to the manner discussed above, fixation screw **63** can be pivoted relative to head **406** and central axis **404** through a range of angles by means of adjustment mechanism **411**. In this regard, control element or worm gear **437** can be accessed through proximal opening **103** at the proximal end of head **406**, for example by insertion of a suitable drive tool (not shown) through opening **103** and into proximal recess **412** and then into drive socket **513** of nut **486**. In order to rotatably unlock locking mechanism **439** and worm gear **437** that rotates one-to-one with driver **511** of the locking mechanism, so as to permit longitudinal movement of sleeve **437** within head **406**, the drive tool is urged distally in drive socket **513** relative to head **406** so as to cause the driver **511** to move longitudinally along axis **404** and thus cause washer second dogs **509** to longitudinally separate and disengage from nut first dogs **501** in the manner discussed above. Once the combined driver **511** and washer **487** unit have been moved to a second position of locking mechanism **439**, the drive tool can be used to rotate driver **511** freely of nut **486** and head **406** so as to rotate worm gear **437** and thus cause the worm gear and sleeve **436** coupled to the worm gear to move longitudinally within recess **412**. In this regard, since the portion of the fixation screw **63** extending through aperture **461** of the elongate member **441** is constrained by sleeve **436**, longitudinal movement of the sleeve relative to head **406** causes the fixation screw to pivot about medial transverse opening **422** of the head **406**.

The construction of head **406** and sleeve **436** provides a particularly robust structure for pivoting the fixation screw **63** in a counter-clockwise direction in FIGS. **68**, **80** and **81**, which for example correlates to reducing a fracture and moving the head **326** of a femur **311** out of varus as shown in FIGS. **57-59** and described above. Such structure also enhances retention of the fixation screw **63** in the desired angular position relative to nail head **406**, for example after completion of the insertion and positioning of the nail **402** Within a bone of a mammalian body and the head **326** of the bone is placed under load when the mammalian body is standing or walking so as to be urging head **326** of the bone into varus and thus exerting a moment on screw **63** in a clockwise direction in FIGS. **67**, **68**, **80** and **81**. In this regard, rounded contact or support surface **428** of nail head **406** engages one side of the shaft **69** of screw **63** and rounded contact surface **471** of sleeve **436** engages the other side of the head **67** of screw **63** in longitudinally spaced apart positions along the length of the screw **63**. The location of rounded contact surface **471** relatively close to the other side of nail head **406**, and outer wall **413** of the head **406**, from nail contact surface **428** provides a relatively large pivot arm for reducing the force exerted on each of surfaces **428** and **471**. Further, the rounded configuration of surfaces **428** and **471**, each of which contours closely to the cylindrical contour of the fixation screw **63**, provides a relatively large surface area at each surface **428** and **471** for disbursing such forces and minimizing large point loads on both of the nail head **406** and the sleeve **436**. For example, when nail **402** is placed within a femur **311** of human, the relatively large loads placed on head **326** of the femur, and thus fixation screw **63**, while the human is upright or walking can be more easily supported by the relatively large moment arm and contact surfaces **428** and **471** acting on fixation screw **63** by nail **402**.

In one embodiment, fixation screw **63** can be pivoted from a first or first extreme position, for example at an angle of approximately 120 degrees relative to head **406** of the nail **402** as shown in FIG. **68**, to an intermediate position, for example at an angle of approximately 130 degrees relative to head **406** as shown in FIG. **80**, to a second or second extreme position, for example at an angle of 140 degrees relative to head as shown in FIG. **81**. When in its first extreme position of 120 degrees as shown in FIG. **68**, fixation screw **63** is further supported during loading by the engagement of cutout surface **426** with screw **63** adjacent rounded contact surface **471** of sleeve **436**. When in its second extreme position of 140 degrees shown in FIG. **81**, screw **63** is extensively supported by the relatively flush engagement of the screw **63**, now in relative alignment with aperture axis **417** of nail **402** and aperture axis **462** of sleeve **436**, by nail circular inner surface **423** forming nail aperture **416** and by sleeve circular inner surface **466** forming sleeve aperture **461**.

Once the fixation screw **63** has been desirable angled relative to nail **402**, set screw **438** can be inserted through the driver **511** into the internally threaded proximal portion **456*a*** of sleeve bore **456** and advanced distally until the rounded end **522** of the set screw engages the fixation screw **63** to lock the fixation screw in its desired angled position and inhibit further pivoting or rotation of the screw **63** within apertures **416** and **461**. In one embodiment, rounded end **522** of the set screw **438** seats within one of the longitudinal slots **204** of the fixation screw **63** for enhancing the rotatable locking of the screw **63** within nail head **406**.

In one method of using the implantable devices of the present invention, for example apparatus **401** and nail **402**, the head of the device can be secured to a targeting assembly or targeting device for inserting the implantable device into a mammalian body. For example, when the implantable device is an intramedullary rod or nail, such as nail **402**, the rod or nail can be secured to a distal portion of a targeting assembly or jig and then directed or placed into the mammalian body with such targeting assembly.

The distal portion of one embodiment of a targeting device or jig suitable for inserting the implantable device of the present invention is illustrated in FIGS. **82** and **83**. Targeting device or jig **531** illustrated therein includes a distal portion **532** having an arm **533** and a connector **534**. In one embodiment, arm **533** terminates at connector **534**, which can include a cylindrical or tubular housing **536** provided with a bore or socket **537** for receiving a connector or fastening element **538**. Housing **536** can have a proximal or upper end **541** provided with a proximal or upper opening **542** to socket **537** for inserting the fastening element **538** into the socket and distal or lower end **543** provided a distal or lower opening **544** through which a portion of the fastening element **538** can extend for securing to the nail head **406**.

Lower end **543** of the housing **536** is sized and shaped to cooperatively engage with the proximal end and proximal opening of nail head **406**. In one embodiment, the lower opening **544** has a diameter approximating the diameter of the proximal opening **103** of nail head **406**. Housing **536** can be further provided with a registering element or key **551** which is cooperatively sized and shaped to snuggly seat within a recess or notch **552** provided on the proximal end of the nail head **406** so as to rotatably lock and register the housing **536** and thus targeting device **531** with the nail head **406** and thus nail **402**.

Fastening element **538** can be of any suitable type and in one embodiment is a cylindrical nut **538** having a diameter closely approximating but slightly smaller than the diameter of bore or socket **537** in housing **536**. Nut can be provided with a through hole **556** extending therethrough. A suitable drive socket **557** can be provided at the proximal end of the hole **556** for receiving any suitable drive element (not shown) for rotating the nut within housing **536**. The exterior of the distal end **558** of nut **538** necks down to a smaller diameter at annular surface **559** and is provided with external threads **561** for cooperatively engaging and threading with internal threads **104** at the proximal end of nail head **406**. Housing **536** is provided with an annular seat or surface **562** in socket **537** for receiving and engaging the annular surface **559** of the nut **538**.

When securing targeting assembly or device **531** to nail **402**, nut **538** is placed in socket **537** of housing **536** and the housing urged again the proximal end of nail head **406** so that housing key **551** registers with notch **552** in the nail head **406**. A suitable drive tool is inserted into drive socket **557** of the nut **538** to screw the external threads **561** of the nut **538** into the proximal opening **103** of the nail head **406**. The housing **536** is urged against and secured to the proximal end of the nail head **406** by the engagement of annular surface **559** of the nut **538** with annular seat **562** of the housing **536**

The securing of the connector **534** of the targeting device **531** to the head **406** of the nail **402** automatically causes locking mechanism **439** of the nail to unlock so as to permit rotation of worm gear **437** and thus movement of sleeve **436** so as to thus permit pivoting of screw **63** relative to the nail **402**. In one embodiment, the distal end **558** of nut **538** has a suitable actuation element of any suitable type such as a cylindrical extension **566** which protrudes distally from such end **558**. The extension **566** can have an external diameter less than the internal diameter of nut **486** of the locking mechanism **439** so as to engage flange **512** of driver **511** of the locking mechanism and simultaneously move the driver **511** distally from its first or locked position, illustrated in FIG. **82**, to its second or unlocked position, illustrated in FIG. **83**, as the nut **538** of the targeting device **531** is screwed into the proximal end of the nail head **406**.

In the foregoing manner, the mere coupling or connecting of the targeting device **531** to the nail unlocks the locking mechanism **439** of the nail and permits the angle of the transverse aperture **416** of the nail, and thus fastener or screw **63**, to be adjusted relative to the central axis **404** of the nail. As discussed above, pivoting of the fastener **63** is caused by inserting a suitable drive element through nut **538** and housing **536** of the connector **534** into drive socket **513** of driver **511**. Prior to such connecting of the targeting assembly **531** to the nail **402** or other implantable device, the locking mechanism **439** is in its locked position so as to preclude angular adjustment of transverse aperture **416** or any fastener **63** therein.

As can be seen from the foregoing, an apparatus has been provided for treating fractures of the femur that marries the fixation attributes of an intramedullary nail with the benefits of a sliding compression screw. The apparatus provides a single device for treating a variety of femoral or other bone fractures, which heretofore have required more than one device. The device can be used to treat a variety of femoral fractures and femoral osteotomies and permits hospitals and manufacturers to reduce the variety of inventories of orthopedic surgical devices and thereby reduce costs. The device allows physicians to move the fracture or osteotomy to a more favorable position after implantation, and for example allows sliding compression of a femoral neck or intertrochanteric fracture. The apparatus permits the physician to vary the angle of one or more proximal fixation screws extending into the head of the femur or other bone, which can be done before insertion or after insertion of the femoral rod into the femoral intramedullary canal. The apparatus can further include one or more additional proximal fixation screws that are nonpivotable relative to the nail and can serve to increase the overall mechanical strength of the apparatus. One or more of such nonpivotal screws can abut one or more of the pivotable fixation screws for inhibiting undesirable post-fixation movement of such pivotable screws and can be further utilized to cause pivoting of such pivotable screws. The device can include a locking mechanism for inhibiting the fixation screw from undesirably pivoting relative to the rod or nail after completion of the procedure.

We claim:

1. An intramedullary rod for use with a fastener to repair a bone in a mammalian body comprising an elongate nail extending along a longitudinal axis and having a stem and a head, the head being provided with an aperture extending along an axis at an angle to the longitudinal axis and adapted to receive the fastener, and an adjustment mechanism carried by the head for pivoting the fastener from a first angled position relative to the head to a second angled position relative to the head, the head including a proximal end and the adjustment mechanism including a rotatable control element carried by the head and accessible at the proximal end for causing the adjustment mechanism to pivot the fastener, and a locking mechanism disposed within the head and accessible at the proximal end that is configured to preclude rotation of the control element when in a first position and permit rotation of the control element when in a second position.

2. The intramedullary device of claim **1** wherein the adjustment mechanism is disposed in the head and includes a sleeve slidable longitudinally relative to the head.

3. The intramedullary device of claim **2** wherein the sleeve is provided with an opening for receiving the fastener.

4. The intramedullary device of claim **1** wherein the locking mechanism includes a first locking element fixed relative to the head and a second locking element movable longitudinally relative to the head between a first position in which the second locking element engages the first locking element so as to be rotatably locked with the first locking element and a second position in which the second locking element is disengaged from the first locking element so as to he rotatable relative to the first locking element.

5. The intramedullary device of claim **4** wherein the locking mechanism includes a spring for urging the second locking element towards the first position relative to the first locking element.

6. The intramedullary device of claim **1** wherein the locking mechanism includes first and second locking elements having cooperatively engageable protuberances which engage and preclude the second locking element from rotating relative to the first locking element when the second locking element is in a first position and disengage and permit rotation of the second locking element relative to the first locking element when the second locking element is in a second position.

7. The intramedullary device of claim **6** wherein the first locking element is a nut having a surface with a plurality of first upstanding protuberances and the second locking element is a washer having a surface with a plurality of second upstanding protuberances which cooperatively engage the first upstanding protuberances when the second locking element is in the first position.

8. The intramedullary device of claim **7** wherein the locking mechanism includes a driver extending through the nut and the washer, the washer being secured to the driver element and a spring disposed around the driver element for urging the washer towards the first position.

9. The intramedullary device of claim **1** wherein the control element includes a screw.

10. An intramedullary rod for use in a mammalian body comprising an elongate nail extending along a longitudinal axis and having a stem and a head, the head having a proximal end and being provided with an opening in the proximal end, a moveable element carried by the head for slidable longitudinal movement relative to the head, a rotatable control element carried by the head and coupled to the moveable element for moving the moveable element longitudinally relative to the head and a locking mechanism disposed within the head and coupled to the control element, the locking mechanism being actuatable through the opening in the proximal end and being configured to preclude rotation of the control element relative to the head for moving the moveable clement when the locking mechanism is in a first position and permit rotation of the control element relative to the head for moving the moveable element when the locking mechanism is in a second position.

11. The intramedullary device of claim **10** wherein the locking mechanism includes a first annular element secured to the head, a second annular element movable longitudinally relative to the first annular element between a first position in which the second annular element engages the first annular element so as to be rotatably locked with the first annular element and a second position in which the second annular element is spaced longitudinally from the first annular element so as to he rotatable relative to the first annular element and a spring for urging the second annular element towards the first position relative to the first annular element.

12. The intramedullary device of claim **10** wherein the locking mechanism includes a first annular element secured to the head and a second annular element movable longitudinally relative to the first annular element between a first position in which the second annular element engages the first annular element so as to be rotatably locked with the first annular element and a second position in which the second annular element is spaced longitudinally from the first annular element so as to be rotatable relative to the first annular element, the first annular element having a surface with a plurality of first upstanding protuberances and the second annular element having a surface with a plurality of second upstanding protuberances which cooperatively engage the first upstanding protuberances when the second annular element is in the first position.

13. The intramedullary device of claim **12** wherein the first annular element is a nut and the second annular element is a washer and wherein the locking mechanism includes a driver extending through the nut and the washer, the washer being secured to the driver element and the spring being disposed around the driver element for urging the washer towards the first position.

14. An intramedullary rod for use in a mammalian body comprising an elongate nail extending along a longitudinal axis and having a stem and a head, a threaded element carried by the head and accessible at the proximal end for rotation relative to the head and a locking mechanism coupled to the threaded element, the locking mechanism including a first annular element secured to the head and having a surface with a plurality of first upstanding protuberances and a second annular element movable longitudinally within the head and having a surface with a plurality of second upstanding protuberances, the second annular element movable longitudinally between a first position in which the second upstanding protuberances cooperatively engage the first upstanding protuberances so as to rotatably lock the second annular element with the first annular element and a second position in which the second annular element is spaced longitudinally from the first annular clement so as to be rotatable relative to the first annular element, the locking mechanism including a spring for urging the second annular element towards the first position.

15. The intramedullary device of claim **14** wherein the first annular element is a nut and the second annular element is a washer.

16. The intramedullary device of claim **15** wherein the locking mechanism includes a driver extending through the nut and the washer and having a distal end, the washer being secured to the driver element and the spring being disposed around the driver element for urging the washer towards the first position, the threaded element having a socket for receiving the distal end of the driver so as to couple the locking mechanism to the threaded element.

17. An intramedullary rod for use with a fastener having a proximal portion and a distal portion to repair a bone in a mammalian body comprising an elongate nail extending along a central longitudinal axis and having a stem and a tubular head, the tubular head having an outer wall and being provided with an aperture extending at an angle to the longitudinal axis and adapted to receive the fastener, the outer wall having first and second side portions spaced oppositely from the central longitudinal axis, the first side portion having a first opening of the aperture for receiving the proximal portion of the fastener and the second side portion having a second opening of the aperture for receiving the distal portion of the fastener, the second side portion having a support surface for engaging the distal portion of the fastener during use and a mechanism carried by the head for engaging the proximal portion of the fastener adjacent the first side portion for pivoting the fastener in situ about the support surface of the second side portion from a first angled position relative to the head to a second angled position relative to the head, the support surface of the tubular head supporting the fastener in the second angled position during use.

18. The intramedullary rod of claim **17** wherein the mechanism is disposed within the head.

19. The intramedullary rod of claim **17** wherein the mechanism includes a sleeve carried by the head and slidable longitudinally relative to the head to engage the proximal portion of the fastener for pivoting the fastener.

20. The intramedullary rod of claim **19** wherein the head includes a proximal end, further comprising a control element carried by the head and coupled to the sleeve, the control element being accessible at the proximal end for moving the sleeve longitudinally relative to the head so as to pivot the fastener.

21. A method for using an implantable device having a head with a proximal end and an adjustment mechanism carried by the head and including a rotatable control element accessible at the proximal end and a locking mechanism that precludes rotation of the control element when in a first position and permits rotation of the control element when in a second position, comprising providing a targeting assembly fir implanting the device within a mammalian body that includes a connector for coupling the targeting assembly to the implantable device and securing the connector to the head of the implantable device, wherein the securing step automatically causes the locking mechanism to move from its first position to its second position.

22. The method of claim **21** wherein the implantable device is an intramedullary rod having a stem and a head.

23. The method of claims **22** wherein the intramedullary device is for use with a fastener and wherein the rotatable control causes the adjustment mechanism to pivot the fastener from a first angled position relative to the head to a second angled position relative to the head.

24. The method of claim **21**, wherein the head is internally threaded and the connector includes a threaded element for cooperatively engaging the internally threaded head and includes a distal end, the securing step including screwing the threaded element into the head to secure the connector to the head and to simultaneously cause the distal end of the threaded element to move the locking mechanism from its first position to its second position.

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